Targeted Risk Assessment: Further Explanation of the Technical Basis of the TRA v3.1

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EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

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European Centre for Ecotoxicology and Toxicology of Chemicals
2 Avenue E. Van Nieuwenhuyse (Bte 8), B-1160 Brussels, Belgium.

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BACKGROUND

Since the introduction of the TRA in 2004, many thousands of users have downloaded the tool and its supporting technical guidance from the ECETOC website. In addition to the guidance contained in the tool's User Guide, ECETOC has supported the TRA via a help facility and has described its technical basis in ECETOC Technical Reports TR93 (2004), TR107 (2009), TR114 (2012) and TR124 (2014).

Since 2010, the worker and consumer modules of the TRA have been used as the basis for estimating human exposures to chemicals within ECHA's Chesar Chemical Safety Assessment (CSA) tool. Because the implementation of software is seldom straightforward, the process for implementing the TRA within Chesar has involved discussions between ECHA and ECETOC. These have aimed at resolving technical issues, but have also served to highlight areas where the available TRA guidance may be strengthened. These discussions led, in part, to the domain clarifications provided in TR124 together with the enhancements relating to the assessment of infrequent uses of consumer products.

This report addresses many of the technical questions that either ECETOC or ECHA have received since 2014 and for which further clarification was thought to be needed or useful. The report also deals with areas aimed at improving the tool's flexibility based upon information that may be available to users.

ECETOC has also continued to review the performance of the TRA, taking part in and advising on a range of studies that have sought to validate the performance of different elements of the TRA, notably the German Federal Institute for Occupational Safety and Health (BauA)-sponsored ETEAM study. Furthermore, via the CEFIC-LRI and other industry science programmes, research has been initiated that further aims to explore the functioning of the TRA. This report summarises some of the key findings that affect the TRA.

1. GENERAL OBSERVATIONS

Since the last updates of both the TRA user guidance and Technical Report 124 in 2014, new understandings on the performance of the TRA have become available, additional user feedback has been received, and ECHA has issued new user guidance on Use Description (Ch R12) and human and environmental exposure assessment (Ch R14-16). This 2017 TRA technical report is intended to capture and reflect the evolution in exposure activities and knowledge over this period. It addresses topics which users have identified as potentially benefitting from further clarification, as well as areas where REACH practice, whether enshrined in ECHA's most recent guidance or in the structure of its Chesar tool, may differ (or be perceived to differ) from the approach taken in the TRA.

This report is the latest in a series that describes the evolution and basis for the TRA model (ECETOC, 2004, 2009, 2012, 2014). This report addresses the TRA v3.1 and it should therefore not be read in isolation but within the broader context of the guidance offered in previous reports, as these describe how and why aspects of the TRA have changed with time.

2. WORKER EXPOSURE ASSESSMENTS

A number of developments have occurred since the previous technical update to the TRA (TR124, 2014). These can be separated into those issues arising from user questions relating to the functioning of the TRA, those resulting from a number of activities that have sought to evaluate the TRA's performance and further definition by ECHA of the use description system which forms the starting point for the exposure estimation algorithms of the TRA.

ECETOC Technical Reports TR93, TR107 and TR114, together with a series of related published articles, describe the evolution and technical basis for the estimates of worker exposure within the ECETOC Targeted Risk Assessment (TRA) model. In addition, all versions of the TRA have been supported by a user guide and a help facility administered through the TRA website. Despite these provisions, it is clear that not all users of the TRA apply the model as intended i.e. within its stated domain. Discussions at ENES (Exchange Network on Exposure Scenarios) and as part of the consultation for Chesar v3 have identified a number of areas where further clarification of aspects relating to the use of the TRA would be helpful for users.

2.1 TRA Domain and Use

2.1.1 Open and closed conditions of use

The TRA makes a distinction between those industrial activities that take place in predominantly closed systems (engineering design results in physical containment with limited potential for emissions) from those that are carried out in 'open' conditions. This distinction reflects the differences in exposure potential associated with these use conditions. This distinction is also intended to supplement the activity description (PROC [Process category] under REACH), which reflects that of a task/process rather than any general condition of use. Two types of activity that occur under closed conditions are identified in the TRA (those associated with continuous operations and those linked to batch activities) whereas 14 different types of 'open' use are addressed. This separation reflects the fact that closed conditions (i.e. those where release of the substance from the process is minimised by engineering controls, supported by administrative controls) are, relative to open conditions, nowhere as near as common.

TR93 contained a more detailed explanation (p.102/3) of those features that differentiate open and closed conditions of use, and TR 107 (p.8/9) and the supporting User Guide for TRAv2 offered further guidance on the topic. What ECETOC has observed, based on anecdotal comments from TRA users and industry sectors, is that there appear to be different interpretations amongst some groups on how to deal with industrial processes that might partly be described by a PROC (coating, dipping, spraying, etc.) but which take place in (fully or partly) closed systems e.g. automated paint spraying that occurs within an enclosure with no or limited manual interventions. Indeed, these different interpretations appear to have been magnified and 'codified' in some supply chains during the development of the supplier/downstream user (DU) Use Maps.

In this respect, ECETOC is aware that for some stakeholders, PROCs 10 and 13 in particular have been the subject of discussion concerning their relevance and interpretation.

Table 1 identifies some of those PROCs that ECETOC has been made aware of and which have been the subject of debate between various stakeholders concerning their relevance and interpretation, together with notes on how ECETOC considers the TRA deals with these situations. Where a PROC is not listed, it is not because there is universal agreement on its meaning or that it is unimportant. It is simply because an 'issue' relating to its interpretation has not been brought to the attention of ECETOC. In general, as detailed in Table 1, in most circumstances it is assumed that systems are open. The TRA is intended to be a screening level tool, and so where PROC activities may take place under a range of conditions the default assumption is that open conditions are possible.

Table 1 : TRA assumptions regarding conditions of use for certain PROCs

PROC[1]	Supporting explanation
PROC 1 / 2	PROC1 and PROC2 are intended to describe the general nature of process exposures in the bulk chemical industry and refining sectors (i.e. respectively, those processes that are fully contained or involve limited manual interventions). While, these situations are typically automated processes or ones that are remotely controlled, they are still activities that may involve some manual intervention (which is the distinction between PROC1 and PROC2). In ECETOC's opinion, therefore, that at a screening level there is no benefit in trying to further differentiate between whether a process is open/manual or closed/automated.
PROC 3 / 4 / 5	PROC3, PROC4 and PROC5 are intended to describe the general nature of process exposures arising from chemicals handling in those industrial sectors using batch manufacturing and processing e.g. fine chemicals, coatings formulation, etc. These situations tend to be associated with a higher (and more intimate) level of manual intervention. Nevertheless, they can also be automated or remotely controlled. In ECETOC's opinion, therefore, that at a screening level there is no benefit in trying to further differentiate these activities into those that are open/manual and those that are closed/automatised.
PROC 8a	PROC 8a refers to the exposures associated with the bulk transfer of substances in general and the TRA consequently assumes that no particular measures are employed to control exposure. Apart from activities involving the general transfer of chemicals, this PROC is often also considered relevant as the starting point for exposure estimation in maintenance activities and similar tasks where the core activity is undertaken in the absence of any established technical measures for reducing exposure. It is noted that in the 2015 version of the Use Description guidance R12, a new PROC (28) is introduced for maintenance and cleaning activities. The TRA does not provide exposure estimates for this new PROC, and users are advised to adopt the values of an alternative PROC such as 8a or similar as before.
PROC 8b	PROC 8b in the TRA reflects the exposures that occur in situations where material transfers are undertaken at locations that are specifically designed and operated ("dedicated facilities") for the transfer to and from vessels that can contain larger quantities (tens of kilos and higher) of chemicals and where the exposure is primarily related to the un/coupling activity and residual emissions from the receiving vessel. Such situations include tanker loading bays and drum filling stations where the core engineering serves to limit emissions and spills e.g. as is often the case in the chemical industry and at formulators. The TRA base estimates reflect the upper end exposures from these situations.
PROC 7 / 11	Although spraying can be carried out under very different conditions (ranging from manual to largely automated processes), the TRA does not distinguish between these various types of spraying. Rather the TRA provides an upper end estimate for the form of spraying most commonly associated with the highest worker exposures. The TRA estimate for volatile liquids is intended to indicate the vapour component, not the aerosol.

[1] Full definitions of the PROCs are contained in ECHA guidance 12 (latest version Dec. 2015, see ECHA web-site)

PROC[1]	Supporting explanation
PROC 9	The estimates for PROC 9 are intended to cover exposures occurring during transfer of substances or mixtures into small containers, typically on filling lines. During the 2015 discussions of the Use Descriptor guidance R12, this PROC was also identified as suitable for the estimation of worker short-term exposure during process or product sampling. Process and product sampling itself can be done with a variety of open and closed technologies. It is usually a brief activity. It is noted that sampling activities are addressed in the R12 guidance as part of process PROCs 1-4, but not for PROC 5. Where there is a need to describe the exposure level resulting specifically from process or product sampling, the TRA estimates for PROC 9 including RMM options can be employed.
PROC 10	Emissions from manual coating operations are considered to be a function of how the coating is applied (e.g. by brush or roller) rather than what type of coating is being applied (e.g. paint, adhesive, lacquer, etc.). The same applies to cleaning agents. The TRA exposure estimates are based on a manual (roller) operation as this is considered the worst case for inhalation exposure. The TRA time weighted estimates account for any associated brush/roller cleaning activities, but where short term hazards are a concern, then these will need to be separately addressed. It should be noted that although the TRA assumes that both sides of both hands will also be exposed, other parts of the body may also be exposed to splashes, spills and aerosols. If there is a likelihood that this will occur, then consideration should be given in the CSA/ES to the communication of suitable additional Risk Management Measure (RMM) advice.
PROC 12	As the PROC12 reflects the use of blowing agents in manufacture of foam (which is typically an “open” activity), the TRA assumes “open” conditions for these activities. Note however that depending on the design of the equipment the exposure potential may be very limited.
PROC 13	While it is recognised that emissions from dipping operations are largely dependent on the extent to which the process may be automated, the exposure estimates for the TRA are based on a manual operation. This is the worst case. In the case where dipping is fully enclosed and automated, then these circumstances are probably best addressed through the assignment of either PROC1, PROC2 or PROC3 to ‘closed conditions of use’ rather than trying to further differentiate the affected ‘open’ PROC to account for how different levels of ‘closedness’ would be applied. It should be noted that although the TRA assumes that the face of both hands will also be exposed, other parts of the body may also be exposed to splashes, spills and aerosols. If there is a likelihood that this will occur, then consideration should be given in the CSA/ES to the communication of suitable additional RMM advice.
PROC 19	The TRA only addresses commonly encountered types of exposure control and does not account for PROC-specific forms of RMM (such as long handled tools). Where users have available data that reliably enables the exposure reduction offered by these types of tool to be considered, then this information could be applied to the base estimates as ECETOC is unaware of any comprehensive body of data that could form the basis for inclusion in the TRA e.g. for use with “manual mixing”.
PROC 28	This PROC was added in the 2015 update of the Use Description guidance R12 to describe ‘Manual maintenance (cleaning and repair) of machinery’. The TRA does not provide separate exposure estimates for this activity. Levels of exposure during this activity vary depending on the type of substance or mixture contained in the machinery and the possibilities to remove the substance or mixture prior to breaking containment, for exampling by flushing or purging. TRA users should note the information provided here above for PROC 8a in relation to possible exposure estimates from cleaning and maintenance activities.

[1] Full definitions of the PROCs are contained in ECHA guidance 12 (latest version Dec. 2015, see ECHA web-site)

2.1.2 Distinction between industrial and professional uses

The TRA originally made no distinction between the industrial and professional uses of a substance. However, following the RIP ‘REACh Implementation Project’ 3.2-2 activity, it was felt that there was a need to distinguish between professional and industrial uses as part of the process for developing a substance’s ‘life cycle tree’. TRA v2 therefore introduced the capability to differentiate the exposure estimates of the two types of use. The basic explanation for the distinction is given in TR107 (p9) and reflects the differences in exposure that are typically associated with the two types of use and which mostly arise from the differences in equipment,

supervision and training that the two levels of enterprise have historically been linked with. With respect to the technical measures that may be implemented to control exposure (such as ventilation), the TRA further differentiates the relative effectiveness of these based on the published 'in use' data. In terms of those other 'software' factors (such as specific task training, operating procedures, supervision, etc.) that are inherent to industrial activities, then these considerations are reflected in the base exposure estimates for either type of use. This distinction in use types is described in Chesar by the use of the flags 'advanced' and 'basic' occupational health and safety management system.

However, the industrial/professional distinction is not always simple and requires some understanding of how different industry sectors are likely to be operated. This type of knowledge best comes from the involvement of occupational hygienists, or those possessing similar skills, to the process of assigning Use Descriptors (UDs) to industrial activities, for example the compilation of supply chain Use Maps. It must be noted though, that the distinction is also driven by environmental emission profiles from these activities, as described in Appendix R.12.3 of the 2015 version of ECHA guidance R12. This appendix also describes examples of typical professional and typical industrial businesses. Finally, it is re-emphasised that the typical conditions of use leading to emissions and exposures in a given situation may not fully align with the broad definitions described above and that the exposure assessor using the TRA may judiciously adopt an alternative set of estimates, such as suggested in R12, page 40, example b (workshops for car repair and finishing).

In addition to the guidance already offered in Technical Reports TR93, TR107 and TR114 (Appendix D), Appendix R.12.3 of Ch R12 (2015) describes a series of examples that are intended to further illustrate these considerations.

It should be noted that in the instances described in R12, the scenario description alone is not always sufficient to be able to reliably assign a relevant PROC and domain. For example, it is also necessary to know how such a substance is being used e.g. if it is a coating then is it via processes that are primarily using spraying, rolling, brushing or dipping? In this respect it is probably prudent to assume that, unless DUs are able to provide confirmation to the contrary, these processes are considered to be professional and not industrial. It should also be noted that where 'industrial' activities are identified, then the registrant is indicating that these are supported by some form of 'established' Occupational Health and safety (OH&S) management system, which could be considered as an Operational condition (OC) that is communicated as part of relevant Exposure Scenarios (ES).

2.1.3 Communication of industrial and professional uses within SDSs

The TRA differentiates between the exposure estimates of industrial and professional uses and reflects the differences in exposure which mostly arise from the differences in equipment, supervision and training that the two levels of enterprise have historically been linked with. The distinction between industrial/professional uses is not always straightforward however and requires some understanding of how different industry sectors are likely to be operated. Indeed, because of this, the manner of how this information is most appropriately communicated to DUs via the ext-SDS/ES should also be considered. In this respect, Table 2 below identifies

those ESCom[2] standard phrases that are currently available and which could be considered to be helpful in conveying some of the exposure control assumptions inherent in the TRA.

Table 2: Communicating industrial and professional uses

Use Type	Available EuPhrac Phrases	Comments
Professional Uses	"Assumes a good basic standard of occupational hygiene is implemented"	Represents the base case of the TRA and equates to use under practices following the basic education and training expected to be provided to employees consistent with the provisions of EU H&S Regulations (notably 89/391/EC and 98/24/EC.) and often promoted by sector organisations in seminars, publications and vocational schemes.
Industrial Uses	No specific 'industrial use' phrase identified	For industrial uses, the TRA assumes a higher level of equipment provision, supervision and training than that which might be typically encountered in professional uses e.g. permanent exposure controls that are subject to systems of routine inspection and maintenance; codification of methods of safe work in procedures and OH&S management systems; etc. It could be argued that, taken together, the application of the phrase "Assumes a good basic standard of occupational hygiene is implemented" together with 'industrial use' implies such a level of sophistication. But the development of a more specific phrase for industrial uses such as "Assumes a higher than basic standard of equipment provision, supervision and training is provided and implemented" may be beneficial.

2.1.4 The Use of OCs and RMMs within the TRA

It has been suggested with respect to TRA inhalation estimates that the Local Exhaust Ventilation (LEV) in TRA may be interpreted more generally as "engineering controls" with a comparable effectiveness. It is similarly argued that such a less prescriptive exposure modifier would increase the utility of the tool regarding inhalation exposure assessments. ECETOC understands this view, but is not able to fully support its implementation within the TRA. This is for two reasons:

1. LEV is the only form of 'engineering control' that is universal across industry and is associated with generally accepted levels of effectiveness (relating to the presumptions that the LEV is properly designed, installed, maintained and operated). Other engineering controls either tend to be specific to a few PROCs/industry sectors and/or are not as well characterised concerning their typical effectiveness. So as these other 'engineering controls' are likely to be more specific to certain situations, they are more typically higher tier considerations and hence there is a far less compelling case for their formal incorporation into the TRA.

[2]ESCom is the acronym for Exposure Scenario Communication. The ESCom standard for the exchange of Exposure Scenario (ES) data between IT systems has been developed by Cefic and DUCC (Downstream Users of Chemicals Co-ordination Group) to enable consistent and harmonised communication of ES information throughout the supply chain.

2. Within the TRA, LEV not only affects inhalation estimates but (when chosen by the user) also those for dermal exposure. While the effectiveness of ventilation as a relevant Risk Management Measure (RMM) for controlling dermal exposures remains a topic of ongoing research (and see section 2.5), few if any data are available to describe the effectiveness of 'other RMMs'.

It has also been suggested by some stakeholders that the LEV in TRA estimates for dermal exposure may be interpreted more generally as "engineering controls" with a comparable effectiveness (to that of LEV) in terms of their ability to reduce dermal exposure e.g. tools/engineering measures to avoid direct hand/skin contact; the impact of automation and containment on dermal exposure potential/estimates; dermal protection (protective clothing) rather than hand protection (gloves); and 'good housekeeping'/cleaning as a means to limit dermal exposure in the case of dust generation. While ECETOC understands the basis of these thoughts, it is not able to support their implementation within the TRA as such controls often are specific to a few PROCs/industry sectors and/or are not nearly as well characterised as LEV concerning their typical effectiveness.

In industry, some combinations of OCs and/or RMMs are highly unlikely or even mutually incompatible. For example, the protection afforded by systems of local exhaust ventilation (LEV) may be lower when used outdoors than when operated indoors, unless supplemented by containment measures. ECETOC has always been conscious of this and has approached the development of the TRA in a manner that has applied OCs and RMMs in a conservative and judicious fashion. So, for this reason, respiratory protection was not included as a RMM as part of v1 and (limited forms of) dermal Personal Protection Equipment (PPE) were only introduced in v3. At the same time ECETOC has built rules into the TRA that determine the manner that certain OC/RMM combinations can be applied (or are excluded) either as a general rule or one specific to defined PROCs. The current exclusions are detailed in TR107 and TR114 and extend to those combinations of RMM and/or OC that are more generally applicable (such as the inability to apply enhanced LEV outdoors; an inability for professional users to apply General Ventilation (GV) in combination with LEV; etc.) as well as those that are specific to certain PROCs (such as LEV having no effect on dermal exposure predictions for PROCs 10 and 19).

Although the basis of these thoughts is understandable, their implementation within the TRA is not currently possible as such controls (and their associated standard phrases) are often specific to a few PROCs/industry sectors and/or are not nearly as well characterised as LEV concerning their typical effectiveness. Moreover, a further complication is that the TRA does not apply consistent RMM efficiencies across every PROC. As such, it is ECETOC's view that implementation of these measures is best dealt with as part of Tier 1+ considerations. If PROC specific RMMs were to be considered to be a desirable feature of the TRA, then this would require the generation of a supporting justification for each PROC/RMM combination (and see section 2.5 following).

Table 3 summarises the relationship between available ESCom standard phrases and some key exposure reduction values contained in the TRA. Although TR107 and TR114 contain explanations for the effectiveness of the LEV, Respiratory Protection Equipment (RPE) and dermal protection values in general, they do not examine whether any specific phrase (or phrase combination) is best linked with any particular situation.

The ESCom phrase library contains a number of phrases that are intended to describe various RMMs and which can be seen to align to the effectiveness of exposure control options contained within the TRA. As can be seen in Table 3 below, phrases do not exist within ESCom for all the RMMs that the TRA is capable of addressing. Furthermore, ESCom only describes certain RMMs (generally the most commonly encountered forms). In such instances where a gap exists or the available phrase(s) is not relevant for a form of exposure control, then users may wish to work with relevant industry associations to develop suitable phrases for adoption by ESCom.

Table 3: Relationship between TRA RMMs and corresponding examples of exposure control

RMM/ OC Type	TRA exposure reduction	Associated ESCom ES SDS phrase(s)	Comments e.g. other phrases that might be usefully communicated in addition
LEV	5x (80%)	No ESCom phrase identified.	
	10x (90%)	Handle in a fume cupboard or under extract ventilation¥ Provide extract ventilation to material transfer points and other openings¥ Provide the operation with a properly sited receiving hood¥ Minimise exposure by extracted full enclosure for the operation or equipment¥ Carry out in a vented booth or extracted enclosure¥ Provide extract ventilation to points where emissions occur¥ Fill containers/cans at dedicated fill points supplied with local extract ventilation¥ Handle substance within a predominantly closed system provided with extract ventilation¥ Provide extract ventilation to emission points when contact with warm (>50oC) lubricant is likely.	¥ represent those phrases that are used in the TRA for industrial and professional uses (90/80%)
	20x (95%)	Minimise exposure by partial enclosure of the operation or equipment and provide extract ventilation at openings	
	>20x (>95%)	Use high-performance fume cupboard Carry out in a vented booth provided with laminar airflow Sample via a closed loop or other system to avoid exposure	

RMM/ OC Type	TRA exposure reduction	Associated ESCom ES SDS phrase(s)	Comments e.g. other phrases that might be usefully communicated in addition
RPE	5x (80%)	None identified.	
	10x (90%)	"Wear a respirator conforming to EN140"; combine with : "Inhalation - minimum efficiency of" [90] %"	
	20x (95%)	"Wear a respirator conforming to EN140"; combine with : "Inhalation - minimum efficiency of" [95] %"	
	>20x (>95%)	No ESCom phrase identified.	
Gloves	5x (80%)	Wear suitable gloves tested to EN374 Combine with: "Dermal – minimum efficiency of [80]%"	
	10x (90%)	Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training Combine with: "Dermal – minimum efficiency of [90]%"	
	20x (95%)	Wear chemically resistant gloves (tested to EN374) in combination with specific activity training Combine with: "Dermal – minimum efficiency of [95]%"	Usually only applicable to industrial settings
	>20x (>95%)	Wear chemically resistant gloves (tested to EN374) in combination with intensive management supervision controls Combine with: "Dermal – minimum efficiency of [>95]%"	Not relevant for professional uses

2.1.5 Increasing the confidence in and extending the choice of OCs and RMMs within the TRA

Questions continue to be raised concerning what represents an appropriate exposure reduction efficiency for any OC or RMM. For example, is it more appropriate that lower (or higher) values than those laid out in the TRA are applied commensurate with the experiences of certain users/sectors or the findings of studies examining the effectiveness of different control approaches within industry? There is no absolute answer to this question. The philosophy that underpins the choice of the current TRA values is set out in TR93 and TR107 (essentially reflecting a situation that is representing good practice i.e. based on the assumption that the OC/RMM is properly designed, applied, operated and maintained) and ECETOC continues to believe this approach is both a defensible and pragmatic basis for the solution to the question. Of course there will be specific circumstances in some workplaces where a particular type of control performs worse (or better) than the efficiency given in the TRA, but the present values are considered to represent ones that are reasonably achievable across a range of industry uses and sectors.

As already mentioned in section 2.1.4, it has been suggested by some stakeholders that the "LEV efficiencies" in TRA estimates can be substituted and interpreted more generally as "engineering controls" with a comparable effectiveness (to that of LEV) in terms of their ability to reduce inhalation (or dermal) exposure. While ECETOC understands the basis of these thoughts, it is not able to currently support their implementation within the TRA, as such controls often are specific to a few PROCs/industry sectors and/or are not nearly as well characterised as LEV concerning their typical effectiveness.

However, ECETOC remains open to suggestions of where further combinations/specifications of this type may help in ensuring that the TRA can continue to be reliably deployed in support of Tier 1 exposure assessments e.g. as part of REACH Chemical Safety Assessments (CSAs). In this respect, and accounting for the positive experiences arising from the previous initiatives on SpERCs (TR107, Appendix H) and SCEDs (TR114, Appendix F), ECETOC can foresee the development of a template that enables a full and transparent justification of assumed effectiveness to be documented for any RMM (or OC) that differs from those contained in the TRA, together with the uses (PROCs) that it is intended to be associated with. This is further discussed in section 2.5.

2.1.6 Dealing with dermal protection under the TRA

Although TRA v1 included recommended approaches for estimating dermal exposures and risks (TR93, Appendix Q), the ability to directly predict dermal exposure as an integral part of the TRA was only introduced in TRA v2 following the emphasis given to this route of exposure during the RIP 3.2-2 activity. The value of 1500 cm^2 exposed skin area was applied in the TRA v1 for those uses where contamination of body surface other than the hands is expected (i.e. spraying activities). The value of 1500 cm^2 was taken from the US EPA Exposure Factors Handbook as a representative value for males that covered the hands and lower forearm (i.e. including the wrists). During the course of the RIP 3.2-2 project, the concept of the Use Descriptors (UD) was introduced. The initial UDs that were proposed included (under the term Process Category or PROC) those 17 worker use types identified in TRA v1. However, further 'missing uses' were identified by stakeholders during the RIP 3.2-2 SEG consultation, resulting in the creation of PROCs 18 and beyond.

In v2 of the TRA, the value of 1500 cm^2 continued to be taken forward for PROCs 7 and 11 (no comments having been made during RIP 3.2-2 concerning the relevance, integrity or otherwise of this parameter). In the case of metals, however, a value of 1980 cm^2 had been assigned by Eurometaux in the development of the exposure estimates for metals[3] and which reflects the value given in Technical Guidance Document (TGD) Ch R15[4]. As the basis for most of the exposure estimates in the TRAv2 were rooted in the Eurometaux studies, then a value of 1980 cm^2 was also applied to be consistent with these studies.

When addressing dermal exposure, it is acknowledged that in some workplace settings, parts of the body (other than the hands) are likely to be significantly exposed. In many of these situations, the exposure arises from exposure to 'high energy' (solid or liquid) particles that are released from the process e.g. spraying, grinding, hand mixing, metal working, etc. Indeed, it could be argued that while the hand is the normal target for dermal exposure, the exposure of other body surfaces is by exception and, more often than not, is confined

[3] http://www.ebrc.de/downloads/HERAG_FS_01_August_07.pdf

[4] http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf

to certain PROCs. For example, where the nature of work may lead to exposure to other parts of the body than the hands (e.g. tasks connected to PROC 6, 7, 10, 11, 13, 17, 19, 24), then not only forms of dermal protection may need to be advised beyond those just for gloves (if these are considered necessary to manage the risk), but engineering controls may also need to be considered.

It is therefore incorrect when using the TRA to interpret the estimates for PROCs 7 and 11 as only referring to the hands: the estimates are also intended to extend to the lower forearm. It therefore follows that any RMMs that are required to manage such exposures will need to address body surfaces other than the hands. Currently, however, the TRA only specifies the effectiveness of the RMM rather than 'selecting' the RMM most appropriate for the situation/PROC. In constructing the CSA for those uses where PROC 7 or 11 apply, it may therefore be appropriate for registrants to highlight this fact e.g. by the inclusion of a phrase such as "If skin contamination extends to other parts of the body, then these areas should also be protected in a manner equivalent to those described for the hands." It must be noted though that the TRA does not allocate such phrases, the responsibility for the development of standard phrases (such as those of EuPhrac), residing with sector groups in industry.

TR114 section 2.3.5 deals with the rationale for the choice of effectiveness of dermal personal protection which acknowledges that there is less information available on the effectiveness of dermal PPE (dPPE) than for respiratory PPE (RPE) and, for this reason, limits the effectiveness of dPPE and restricts some forms of dPPE to only industrial uses. TR114 addresses both gloves and gauntlets (i.e. those forms of PPE having a greater bearing for PROCs 7, 11 and 13). Reports TR107 and TR114 also examine the influence of extraction ventilation on dermal exposure. The TRA does not address other engineering controls that are designed to limit or prevent dermal exposure/ contact as there is a paucity of such information and is insufficient to be reliably applied across a range of settings/PROCs.

Table 4 identifies those PROCs most likely to be associated with 'other than hand' dermal exposures; and the body surfaces most typically associated. One way by which the integrity of the CSAs for these uses could be improved could be that these PROCs are 'flagged' in the TRA as being ones where any CSA should be extended to include some qualitative CSA addressing associated exposures and/or RMM options. For example, the ESCom phrases "Wear suitable coveralls to prevent exposure to the skin" and "Other skin protection measures such as impervious suits and face shields may be required during high dispersion activities which are likely to lead to substantial aerosol release, e.g. spraying" already exist. These, or the suggested generic phrase "If skin contamination extends to other parts of the body, then these areas should also be protected in a manner equivalent to those described for the hands" could then be communicated as a form of extended base case. However, it is also possible to develop these ideas further (such as using different/more specific phrases for different PROCs such as those indicated in Table 4), albeit with the consequence that communications in this area would become more complex (e.g. where more than one PROC is associated with an activity) with all the attendant considerations that this brings.

It must be noted though that, to date, ESCom has not developed such phrases and the responsibility for initiating them resides with sector groups in industry.

Table 4: Possible relationship of PROC to dermal exposure

Affected PROC	Body surfaces other than hand/wrist	Possible additional qualitative CSA/ standard phrase
Generic approach		
Any PROC listed below		If skin contamination extends to other parts of the body, then these areas should also be protected in a manner equivalent to those described for the hands
PROC specific approach		
6*	Torso, forearms	Provide suitable protection against skin contamination for the body and forearms to an equivalent standard to that described for the hands
7*	Torso, thighs, face	Provide suitable protection against skin contamination for the body, face and forearms to an equivalent standard to that described for the hands
10¥	Forearms	Provide suitable protection against skin contamination for the forearms to an equivalent standard to that described for the hands
11*	Torso, thighs, face	Provide suitable protection against skin contamination for the body and face to an equivalent standard to that described for the hands
13	Torso, thighs, forearms	Provide suitable protection against skin contamination for the body and forearms to at least an equivalent standard to that described for the hands
17*	Torso, thighs, forearms, face	Provide suitable protection against skin contamination for the body, face and forearms to an equivalent standard to that described for the hands
19	Forearms	Provide suitable protection against skin contamination for the forearms to an equivalent standard to that described for the hands
24*	Torso, forearms	Provide suitable protection against skin contamination for the body and forearms to an equivalent standard to that described for the hands

* indicates that much of the dermal exposure tends to be indirect and hence capable of being reduced by enhanced worker training.

¥ The description of PROC10 includes wiping along with brushing/rolling. Because wiping entails intentional direct contact with the substance/preparation, then additional consideration may need to be given to such tasks and the nature of associated dermal exposures/risks.

2.1.7 Solids in liquid products

As explained in TR114, the TRA was not originally developed for sector-specific complex exposure assessment needs such as the estimation of inhalation exposures to 'solids in liquids' because, for the reasons stated (in section 2.2.7), the relationship between concentration of the solid substance in the liquid product and inhalation exposure to the substance cannot be concluded to be linear i.e. for scenarios which involve the spraying of formulations or similar situations where the solid exposure occurs in the form of aerosols, then exposure is independent of the physical form of the pure solid. However, if users wish to make such predictions using the TRA, then as a default setting for this type of product, ECETOC would advise the use of the high dustiness estimate in conjunction with the concentration modifier independently of the physical state of the pure solid. Any further refinement for those scenarios not resulting in aerosol formation for which the assessor

wishes to account for the non-dusty character of the solid contained in a liquid will need 'calibration' with information such as from actual measurements.

Concerning dermal exposures, similar to the inhalation exposure estimates and although the TRA does not require the differentiation of physical form as an input, by default some users have assumed that solids-in-liquids are covered. This is not the case and dermal exposures to solids in liquids were not originally intended to be covered by the TRA. However, the recent study by Marquart et al (2017) on the dermal estimation of the TRA indicated that, based on a limited set of exposure studies, TRA predictions appear conservative when compared to measured data for solids-in-liquids. These findings are encouraging, but are not sufficiently representative to justify any broadening of the current scope of the TRA at this time.

2.1.8 Predicted exposures above the substance SVP

Some users have reported that for some substances with low vapour pressures, the TRA predicts exposures that exceed the Saturated Vapour Pressure (SVP) for the substance. This phenomenon is not new and is addressed in TR107 (Appendix D) and TR114. Indeed, changes were introduced in v3 of the TRA (section 2.2.4 of TR114) to reduce the number of substances impacted. However, despite the changes, for some substances with low (and very low) vapour pressures, the TRA will continue to predict exposures that exceed the SVP for the substance.

2.1.9 Physical states outside the boundary of the TRA

Some Chesar users have expressed a desire that the domain of the TRA be extended to accommodate certain types of use that are not currently supported by the TRA e.g. where molten solids are handled. Although section 2.2.5 of TR114 discusses how elevated process temperature for volatile liquids can be addressed by users in the absence of simple, reliable and widely applicable algorithms to more extensively model these situations, then molten liquids remain outside the domain of reliability for the TRA.

It has also been reported that the TRA has been applied to predict (inhalation and dermal) exposures to solid objects. The TRA is not intended to cover inhalation and dermal exposures in relation to the handling of solid objects, other than where these objects are subjected to activities like cutting, rolling etc, in which case the exposure estimate is intended to reflect the fraction released by these activities, as described by PROCs 21 and 24. For other scenarios, where the release is by diffusion or a dissolution process during normal handling, available experimental data at the time of TRA development were insufficient to derive meaningful exposure estimates. Therefore, when solid objects are being handled outside PROCs 21 and 24, then deriving an estimate through the application of the low dustiness category is unlikely to yield a reliable and accurate estimate of worker exposure.

2.1.10 Gases and liquefied gases

The TRA does not predict exposure to gases. This is because exposures to gases can rapidly rise to high concentrations, dependent on the amount in use and level of containment. As a Tier 1 tool, the TRA does not

account for quantity. However the TRA does allow exposures to very volatile liquids (with no upper bound set on vapour pressure) to be estimated. As these very volatile liquids might be assumed to be the equivalents of gases for many circumstances of use (PROCs), then provided users are able to assure themselves of such equivalencies, it is reasonable to assume that the high volatility exposure prediction can also be used to predict exposures to gases in certain scenarios.

It should be noted that when applying the high volatility estimate, it is really only likely to be relevant for those PROCs which do not describe open conditions of use as handling gases in such circumstances will frequently be associated with significant safety considerations. Safety is the predominant concern although very high health hazardous concentrations can rapidly occur.

2.2 Differences between the TRA and Chesar v3.2

Although both ECETOC and ECHA have received questions relating to the perception that there are major differences between the Chesar implementation of the worker TRA and the ECETOC web version, such differences are minor and are summarised in Table 5 below.

Table 5: Summary of identified differences between TRA v3.1 and Chesar v3.2

Issue	Comment
At face value, Chesar appears to apply a default temperature for workers of 40 Celsius whereas the TRA applies 20 Celsius in the base case. Does this mean Chesar predictions will be higher than those of the TRA?	Chesar does have a default operating temperature of 40°C but ECHA advises sectors developing Specific Worker Exposure Determinants (SWEDs) to set the operating temperature to a reasonable one depending on the use. Also single registrants may adapt the operating temperature. Chesar will then estimate the exposure based on -A vapour pressure recalculated at the operating temperature if the latter is below 40°C (with the exception of PROC 6) -Using the highest fugacity by default if the operating temperature is above 40°C (with the exception of PROC 6) but giving the assessor the possibility to provide the vapour pressure at the operating temperature Therefore these characteristics are unlikely to result in any change to TRA predictions between the standalone tool and Chesar.
Chesar allows for the exposure modifier for concentration to also be used for solids in liquids. How does this fit with ECETOC's guidance on solids in liquid products?	The TRA standalone does not include the facility to estimates 'solids in liquids' as explained in TR114. This is because, for the reasons stated (in section 2.2.7), the relationship between concentration and exposure cannot be concluded to be linear. However, applying the TRA concentration bands for the solid component is both conservative and non-linear.

2.3 TRA Inhalation Estimates

Since the release of the TRA v1 in 2004, the performance of the TRA has been assessed by a number of different study groups by comparing the TRA estimates with measured exposure values. However, the ability to

interpret these studies beyond a narrow set of conditions has been hindered by the fact that, not least, they often contain low numbers of samples. Following the widespread use of the TRAv2 in the 2010 REACH registrations, the German Federal Institute for Occupational Safety and Health (BauA) initiated a study in 2011 which aimed to compare the most common models used to estimate worker exposure under REACH (ETEAM project[5]).

In 2014, the BAuA held a workshop that reported on the findings of the project (see ETEAM reports[6]). ECETOC was a member of the ETEAM's advisory board. Unfortunately, the lack of suitable exposure measurement datasets prevented any analysis of dermal exposures as well as constraining the scope of the study, as it was only able to examine comparatively few exposure situations (PROCs) in any depth. Moreover, resource constraints meant that many of the suggestions put forward by ECETOC (as well as other advisory board members) concerning the preferred methods for analysis and comparison were not able to be incorporated into the ETEAM methodology. This meant that there are significant shortcomings to the ETEAM study as it relates to its ability to derive robust conclusions regarding the TRA's performance. At the time of the publication of the study reports (Dec 2015), ECETOC summarised its reservations about the study and shared these with BauA and other stakeholders (see Appendix 1 of this report).

Despite these shortcomings, there are areas of the ETEAM findings that are worthy of further research and discussion. For example, the ETEAM findings suggested that the TRA's performance is stronger for certain uses and substance types than for others. But, at the same time, these findings are not necessarily consistent with those from other researchers and/or other models also examined within the ETEAM activity. The ETEAM also touched on the topic of how conservative any model might be: clearly the higher the conservatism, the less likely any model will underestimate measured exposures. But conversely, higher conservatism is also probably less useful if the exposure predictions have no bearing on reality. What is required is a situation where the predicted exposures can be seen to be reasonably conservative representation of the defined population(s).

In early 2016, BAuA made available the database used by the contractors who undertook the ETEAM analyses. This provided an opportunity for ECETOC to explore in more detail the underlying data and methods of analysis behind the ETEAM findings. The focus of this re-analysis was put on PROCs where the ETEAM findings suggested issues, provided the data sets were reasonable. The exercise was carried out by three groups of 2 experienced assessors producing consensus estimates. The ECETOC analysis identified a number of aspects of the ETEAM data compilation and analysis by BauA's contractors that impact the ability to draw conclusions from the study. Re-analysis considering these aspects does lead to identification of some areas for improvement, but also changes some of the reported study conclusions.

While the ETEAM database was found to contain a significant number of sample data points, these derived from only a limited number of data sets, of which only a small number contained ≥ 6 data points (the minimum number that might reliably be used to describe the exposure distribution of a working group). This meant that the scope of the database is limited compared with the coverage of REACH and the TRA. However, the database does contain sufficient information to enable the estimates to be re-constructed.

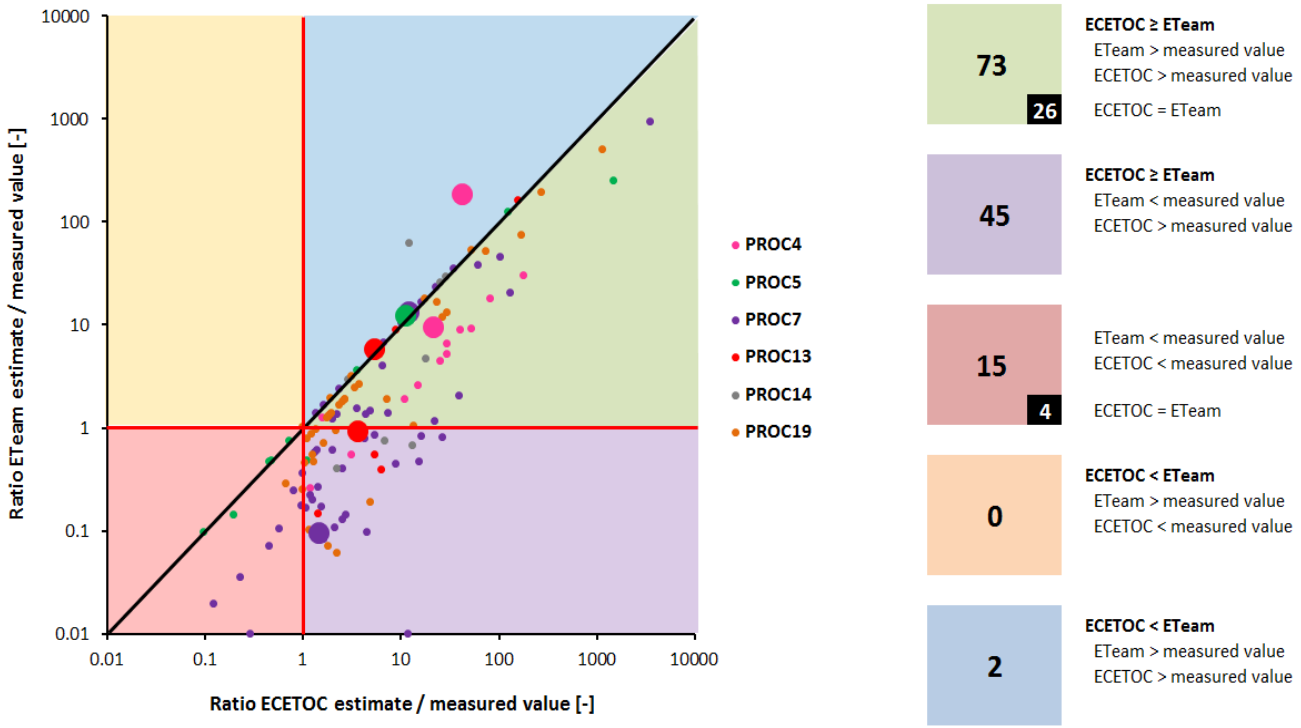
[5] http://www.eteam-project.eu/

[6] http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Workshops/ETEAM-2014/ETEAM-2014.html

Here, the ETEAM methodology and basis for TRA model validation was found to be problematic. The TRA provides a 75th percentile estimate for an identified work group (as described by the PROC). Therefore, not only should any analysis of the TRA be based on datasets of sufficient size that enable a P75 to be meaningfully determined (e.g. ≥ 6 data points), but the comparator should also be at a similar level of confidence. In this respect, the underpinning database used by the ETEAM was also deficient; many instances were identified where datasets have few samples and are not sufficiently robust to draw critical conclusions, hence a few datasets appear to heavily weigh on overall findings; no 'statistical test' of fit had been applied to determine if the datasets can be considered representative or not; and many cases were identified where the data appeared to have been incorrectly interpreted for comparative analyses, for example where REACH Use Descriptors were incorrectly applied. Taken together, all this materially affects the nature of the associated ETEAM findings. Unfortunately, Use Maps, which could have helped the ETEAM researchers in assigning proper TRA parameters, did not appear to have been referenced in the study.

A summary of the re-analysis findings was presented at the ISES Conference in Utrecht in October in 2016 (See Appendix 2) and a summary of the analysis is presented in Figure 1. In this analysis, the original ETEAM value for measured exposure was compared to the measured value from the re-analysis following appropriate PROC and use condition grouping (y axis). The ECETOC TRA estimate was also compared to the measured value from the re-analysis (x axis). When a given PROC has multiple points associated with it, this reflects differences in available data sets. The size of the dots indicates whether the data set had more than 6 data points (large dot) or less (small dot).The colour coding of areas within the plot reflects different combinations of how the ECETOC estimated exposure compares to the original ETEAM value for measured exposure, and also of how they each compare to the measured exposure following ECETOC re-analysis of measured values.

Figure 1: Summary of ECETOC Re-Analysis of ETEAM Database



The findings in Figure 1 suggest that the ETEAM conclusions relating to the TRA's underestimation of some PROCs to be premature and less severe than reported by ETEAM. It is clear, however, that the conclusions in the ETEAM report require further examination and discussion. In this respect, the CEFIC LRI programme has recently initiated research aimed at securing a more comprehensive understanding of the TRA's performance, using a combination of field and laboratory studies. ECETOC has shared the details of the re-analysis with stakeholders, as the corrected assignation of relevant PROCs and scenarios based upon consensus of experienced REACH assessors is relevant not only to the TRA assessment, but also to the ETEAM's assessment of other REACH exposure models.

One finding that the ETEAM study identified was the significant variation in the outputs that can arise from different TRA users if users do not properly understand the tool or are familiar with the basis of the REACH Use Descriptor system. This finding is not new and its fact has been previously highlighted by ECETOC (Money et al, 2014). One reason why the TRA domain is clearly stated in the Technical Reports and User Guide is to help minimise such variation. The concepts of Generic Exposure Scenarios (GESs) and Use Maps (UMs) that were developed by CEFIC in 2008-10 were also intended to address this challenge and to reduce such variation. Furthermore, ECETOC proposed the concepts of SpERCs (TR107, 2009) and SCEDs (TR114, 2012) in order to help further refine TRA estimates in these areas. Recently, the ECHA supported ENES activity has endorsed the Use Maps, including referencing relevant SCEDs, SpERCs and SWEDs, many of which are to be found posted on the ENES website[7].

A further finding of the ETEAM study was the difference between the effectiveness of workplace extract ventilation (LEV) assumed within the TRA and that encountered in practice and which, in part, help to explain why the TRA estimates were found to be less than measured values in some circumstances. The TRA provides a conservative estimate based on the performance that might reasonably be assumed if the LEV is properly designed, installed, maintained and operated (i.e. in accordance with the requirements of current EU workplace health regulation). The ETEAM study identified that LEV in practice very often operates at lower performance levels. This aspect is explored in more detail later in this report.

2.4 TRA Dermal Estimates

Due to a paucity of dermal exposure measurements, the ETEAM did not investigate this aspect of the TRA. However, CEFIC-LRI initiated a project in 2015 with such an aim. From among a number of potential research groups, TNO in the Netherlands were chosen to undertake this task. TNO reported their findings in late 2016 and has subsequently published them (Marquart et al, 2017). The TNO analysis correctly compared TRA predictions with the 75th percentile of the workgroup (PROC), rather than relying on statistics based on individual samples. Applying such an approach results in many datasets having to be discarded as they contain insufficient sample numbers on which to reliably derive statistical distributions. Although only a limited number of dermal data sets (n=110) were identified, covering only a limited number of PROCs (albeit those with the most likelihood of dermal exposure), the analysis suggests that the TRA performance is generally consistent with a Tier 1 tool (over 80% of predictions exceeded the 75th% of the measured values across all substance types) and has a clear bias towards severe overestimation (by up to 2 orders) of dermal exposure

[7] https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

at low measured exposure values while all cases of apparent underestimation by the TRA occurred at high measured exposure values. The overestimation of exposure at lower levels can partly be explained by a built-in bias in the TRA on the effect of concentration of substance in product used, duration of exposure and the use of protective gloves. Indeed, the TNO data suggested that the protection afforded by gloves to be an average factor of 34, while factors of between 5 to 10 are used in the TRA estimations.

While the TNO findings relating to the TRA can be seen to be reassuring, they are also associated with a high level of uncertainty caused by the paucity of good quality sets of dermal exposure measurements. Insofar as those areas of the study where underestimations were found to occur, then these were associated to a large extent in situations with very high skin contamination due to e.g. dipping (part of) hands in a liquid, working in a cloud of dust or having contact with heavily contaminated surfaces i.e. circumstances that are not commensurate with basic occupational hygiene practice. Indeed, the TNO study highlights many of the factors that constrain the ability of available exposure measurements to be used beyond the specific circumstances in which they were obtained. Because dermal exposure constitutes a significant exposure route for many activities and types of chemicals, a better exchange of information between the activities of industry, the regulatory community, academia and other stakeholders would appear to be warranted if definitive conclusions are to be drawn on the nature of dermal exposure to chemicals and those models (such as the TRA) that aim to estimate such exposures.

2.5 The Use of Alternative RMMs

The effectiveness of Risk Management Measures (RMMs), particularly extract ventilation, within the TRA has been fixed at a level that represents what might be reasonably achieved by users if the RMM has been properly designed, installed and maintained and that workers are trained to use it correctly. The protection that the TRA assumes to be afforded differs between professional and industrial users. In preparing v3 of the TRA in 2011/12, ECETOC became aware that some industry groups hold information that suggests that higher efficiencies can be obtained when certain types of RMM are applied. As these forms of RMM tend to be specific to a type of industry or substance, ECETOC has encouraged these groups to make this type of information publicly available. In this respect, CEFIC has initiated an activity that aims to catalogue such RMMs and the European solvents group, ESIG, has recently published a study that describes the effectiveness of a number of 'alternative RMMs' for managing exposures to volatile solvent (ESIG RMM study[8]).

Together with the experiences from SPERCs and SCEDs, it is apparent that for such initiatives to be successful, then the information being shared needs to be of a suitable quality and transparency if it is to be capable of being reliable applied and satisfy the expectations of stakeholders. In particular, the experiences indicate the reported data should be able to describe/define the RMM or OC (e.g. engineering controls, effect of automation or containment, effect of specific worker training, etc.); describe/define the PROCs to which the RMMs/OCs are applicable; based on the available (and referenced) data, describe the effectiveness of the OC/RMM/PROC combinations; and, ideally, identify available sets of phrases (single phrases or "control packages") that describe the sector/task/process specific RMMs suitable to achieve the assumed effectiveness (or suggest these where they may be lacking).

[8] http://www.esig.org/uploads/ModuleXtender/Publications/231/Overview_and_summary_of_report_for_inclusion_of_ESIG_GES_Worker_webpage.pdf

The SPERC and SCED experiences also indicate that it is better to have a standardised template in which such data can be shared in order to maintain consistency. The hope is it would be populated by those industry groups with an interest in the RMM/OC, as well as through contributions from academia and elsewhere, and could then be suitably evaluated and promoted e.g. via ENES and/or EU-OSHA etc. Appendix 4 describes a potential template that could be applied (and which derives from the recent CEFIC-LRI B15 project[9] on RMM efficiency, accounting for the experiences of SPERCs and SCEDs), although it derives from a research activity and hence may benefit from further discussion within suitable stakeholder fora before any widespread application.

[9] http://cefic-lri.org/projects/b15-ucran-developing-a-robust-method-of-allocating-efficiency-measures-to-regulatory-instruments-in-the-chemicals-industry/

3. CONSUMER EXPOSURE ASSESSMENTS

3.1 Explanation of the Technical Basis for the ECETOC TRA Stand-Alone Consumer Module

Since release of the ECETOC TRA v3.1 in 2014, several developments have taken place both in the progression of Specific Consumer Exposure Determinants (SCEDs) and in ECHA's release of an updated version of Chapter R15 Guidelines for Consumer Exposure Assessment (will be referred to as R15v2016). It is well recognised that the duration and frequency of exposure and hazard should be aligned in order to combine the two into a risk estimate (ECHA 2012, ECETOC 2003, ATSDR 2005, IPCS/WHO 2010) and both SCEDs and R15v2016 help to address the challenge of comparing infrequent and/or short duration exposure estimates to a long-term systemic Derived No Effect Level (DNEL) value, as specified in REACH risk characterisation guidance. The TRA v3.1 release preceded R15v2016, and includes an optional approach which directly adjusts the exposure estimate based upon the frequency information within a SCED. The R15v2016 guidance includes an approach where the frequency and duration information within a SCED can be used to adjust the DNEL hazard component. The difference in approaches can lead to confusion, particularly as the consumer TRA within Chesar allows implementation of R15v2016 guidance, whereas this has not been incorporated into the stand alone ECETOC TRA consumer module. This section therefore serves to clarify the approach taken to exposure duration and frequency in the TRA.

In order to better match temporal aspects of exposure and risk metrics, exposure tools often present multiple metrics, such as event exposure, day of use exposure, and average annual lifetime daily doses. Understanding what is the most appropriate type of hazard benchmark (Table 6) requires understanding the results of the toxicological studies. By definition, a long-term systemic DNEL for general population represents an exposure level present for 24 hours/day over a lifetime at which no effect is expected (ECHA, R15, p. 17 Section 15.2.3.a). If a substance can exert an effect following a single exposure event, then an acute DNEL should be provided. If a substance has an effect unique to the area of external contact, then a local DNEL should be provided.

Table 6: General Population DNELs based upon ECHA Table R.8-1

Exposure Pattern	Units
Acute – inhalation, systemic effects	mg/m^3
Acute – dermal, local effects	mg/cm^2
Acute – inhalation, local effects	mg/m^3
Long term – dermal, systemic effects	mg/kg
Long term – inhalation, systemic effects	mg/m^3
Long term – oral, systemic effects	mg/kg
Long term – dermal, local effects	mg/cm2
Long term – inhalation, local effects	mg/m3

Within the TRA tool (ver3.1), an optional approach has been developed in which the exposure estimate can be adjusted to better align with the temporal aspects of the hazard metric, particularly with the use of SCEDs.

On a default basis, the event exposure is compared to the specified DNEL, which has been required to be a long term systemic DNEL for REACH, and daily use is assumed. If this initial analysis results in a Risk Characterisation Ratio (RCR) >1, and SCEDs exist to support that use is infrequent, then a frequency banding approach is applied in which the exposure estimate can be reduced by a given factor associated with its frequency of use, and this reduced exposure compared to the long term systemic DNEL.

The advantage to this adjustment approach of modifying the exposure side of the equation to better match the hazard metric is that the TRA calculates both exposure and risk, but with a supplied DNEL (in other words, the TRA is an exposure estimation tool and does not calculate or derive DNEL values). **The details of DNEL derivation are not likely to be known to the TRA user – for example, the values or basis of assessment factors used in its derivation, the length of the study which form the basis for the DNEL, if it is a 1.5-2 year study whether or not higher concentrations exhibited effects at shorter durations or only at study termination. Without this information, having TRA users apply adjustment factors to the DNEL could add uncertainty, variation, or inconsistently back-adjust for factors used in DNEL derivation (see below for more discussion on this). The TRA user will, however, have the SCEDs and be able to match the exposure metric to the relevant DNEL.**

Regarding alignment of the TRA estimate with long term systemic DNELs, we note that while long term systemic DNELs are expressed in external air concentration units (mg/cm^3), long term systemic effects are related to internal systemic dose (mg/kg/day basis). For inhalation exposures from events < 24 hours in duration, using the event air concentration (as in the TRA tool) provides an extra margin of safety into the risk characterisation. For example:

- Assuming a 1 m^3/hour inhalation rate and 60 kg body weight and a 1 hour exposure event of 120 mg/m^3, and that 100% of the substance present in the inhaled volume is absorbed, the exposure is 2 mg/kg/day.
- If the long term systemic inhalation DNEL, which is based upon a 24 hour exposure for the general population, is 120 mg/m^3, this indicates an allowable internal dose estimate of 48 mg/kg/day. **The RCR for the air concentration of the exposure event would be 1, but on a mg/kg/day basis would be 0.04. As the TRA calculates an RCR based upon the event concentration, it would result in the RCR of 1 rather than 0.04.**
- If the event concentration were averaged over the 24 hour day period, the time weighted average concentration of 5 mg/m^3 extended over a 24 hour period would result in a systemic dose of 2 mg/kg/day, the same as that of the exposure event. Both the 24 hour TWA and the daily dose provide RCRs of 0.04.

Implementation of a 24 hour Time Weighted Average (TWA) air concentration has no impact on the estimated daily dose, only on the external air concentration. Situations in which the external air concentration is key, i.e., local effects caused by irritating or corrosive substances as well as acute effects, should be compared to the appropriate DNEL. If a toxic effect is systemic, as indicated for comparison to the long term systemic DNEL, the internal dose is a more appropriate metric to consider. Thus, it is important to understand the toxicological basis of the health effect being protected for, and to have hazard benchmarks that appropriately reflect potential impacts.

The TRA approach does not adjust for daily duration, but allows for use of a frequency factor (Table 7) that can be applied to an infrequent event exposure estimate, when this value is being compared to a long term systemic DNEL.

3.1.1 Frequency (Banding) Approach in the TRA Consumer Tool

As a default, all scenarios in the TRA assume a frequency of daily use (or multiples uses per day in the case of air fresheners). Thus, no frequency adjustments are applied in the default-based version of the TRA. Refinements offered by Specific Consumer Exposure Determinants, however, include consideration of frequency. In order to fully utilise the information value of the SCEDs, the TRA includes the option to implement a frequency banding approach, accounting for Low Frequency Events (i.e. < daily, Table 7 below).

Table 7: Frequency Banding Approach in TRA

Frequency of Use	Definition	TRA Exposure Multiplier	Rationale for Multiplier
Frequent	Event occurs at least once a week	1	Equates to daily use.
Occasional	Event occurs between once a week and once a month.	0.2	Exposure reduction factor reflects that average exposures are expected to be at least one order of magnitude less than daily exposures.
Infrequent	Event occurs between once a month and once every 6 months.	0.04	Exposure reduction factor reflects that average exposures typically expected to be at least 50 fold less than daily exposures.
Very infrequent	Event occurs no more than once in 6 months.	0.01	Exposure reduction factor reflects fact that average exposures expected to be at least two orders of magnitude less than daily exposure.

This approach is consistent with that employed by other consumer exposure models, i.e. ConsExpo, E-FAST, where long term average daily doses are estimated by considering the frequency of occurrence per year. The day-of-use exposure is multiplied by the frequency per year and then divided by the number of days per year for an annual average. The TRA considers only the annual average; it does not include calculation of a Lifetime Average Daily Dose (LADD) as found in some models, in which the annual average is then further reduced by multiplying by the number of years in which exposure occurs divided by the years in a lifetime. As Table 8 indicates, the TRA factors for calculation of annual averages are similar or more conservative than the values that would be applied if the actual frequency was used. It should also be noted that use of a conservative estimate for the frequency itself (based upon higher end of frequency range) provides a starting point that is already meant to be conservative (and hence consistent with a Tier 1 model), especially for products that are not likely to be used on an annual basis (for example, some 'Do It Yourself' products).

This approach is valid for endpoints where effect is related to the cumulative dose. The adjustment may not be applicable where dose rate is an influential factor in toxicity (for example, genotoxicity, immune reaction induction, or reactive chemistries). It is important to note that the exposure estimates obtained with the consumer TRA tool are primarily intended for assessment of systemic effects. They are not meant for assessing local effects such as allergic sensitisation or irritation. To assist in appropriate application of this feature in the TRA tool, domains of use are provided (Inset 1).

We note that the frequency banding approach is applied to a TRA exposure estimate that has multiple screening level aspects. This factor is applied to the event external air concentration for inhalation. For substances with Vapour Pressure (VP) > 10 Pa (pascal unit), the event inhalation exposure estimate is based upon 100% of the substance weight fraction volatilising instantaneously. For scenarios where dermal or ingestion exposure occur, these routes are in addition to inhalation (i.e., mass balance is not maintained - substance is considered on skin or ingested in addition to 100% in air). For each exposure route, the event exposure estimate is based upon factors intended to result in a conservative value.

Table 8: Comparison of TRA frequency band values with frequency of use

Frequency of use	Frequency (days/year	Factor if used actual frequency (days per year/365)	Ratio of TRA Band factor divided by Actual Use frequency Factor
Frequent	52 – 365	0.14 – 1	1 – 7
Occasional	12 – 52	0.03 – 0.14	1.4 – 6
Infrequent	2 – 12	0.005 – 0.03	1.2 – 7.3
Very Infrequent	1 - 2	0.003 - 0.005	1.8 – 3.6

3.1.2 Duration Approach

Within the TRA, there is no explicit consideration of exposure event duration for the dermal or oral routes, nor for the inhalation route for event concentrations expressed on a mg/m^3 basis. The inhalation event concentration is based upon instantaneous release of the weight fraction associated with a given vapour pressure band (100% for VP > 10 Pa). The TRA does allow for some air exchange (based upon residential rates without active ventilation) and the total amount of dilution resulting from the air exchange will depend upon the duration.

Event durations within the TRA ranges from 0.3 to 8 hours across scenarios. It is recognised that comparing an inhalation event concentration to a DNEL that represents an allowable long-term 24-hour concentration is a conservative approach. This conservatism is further compounded by the assumption that all material is released at the instant the event starts. And for scenarios with multiple exposure routes, for substances with VP greater than 10 Pa, exposure is further over-estimated by the approach taken that even though 100% of the substance is present in air, it also remains present in the portion of product that is dermally or orally contacted.

Note, for inhalation the mg/m^3 value is used for RCR calculation, and this RCR is added to values for the dermal and oral routes to calculate the total RCR across routes. The TRA, however, also provides the inhalation exposure in mg/kg/day so that a total daily exposure in mg/kg/day from all exposure routes could be estimated.

For the inhalation route, when exposure is expressed in mg/kg/day, then the total dose on a body weight basis is calculated considering the amount present in the volume of air inhaled for the duration of the exposure event. This approach is a simple unit conversion; it is not an application of modifying factor, but rather a realistic estimation of exposure in the units of mg/kg/day.

Inset 1: Domains of Use for Frequency Banding Approach in TRA

The TRA was developed as a screening level exposure and risk assessment tool.

TRA develops exposure and risk estimates based upon the event exposure. The event exposure is expressed on a mg/kg/day basis for dermal and oral routes, and a mg/m^3 concentration for the event duration for inhalation. The event values are compared to DNEL values, generally for long term systemic effects.

The TRA includes a feature where for infrequent exposures (<1/week) an adjustment factor can be applied to reduce the exposure estimate for comparison to the long term systemic DNEL. However, in the presence of a short term systemic or local DNEL value for a substance, this should also not be exceeded. Frequency factors cannot be applied to short term DNEL- values.

It is important to note that the exposure estimates obtained with the consumer TRA tool are primarily intended for assessment of systemic effects. They are not meant for assessing local effects such as allergic sensitisation or irritation. They are also not meant to cover physical hazards (e.g., corrosivity, flammability, reactive chemistry[10]). All of these endpoints may need to be considered separately.

Users of this feature should take into account the following application boundaries:

1. It would be expected that the user of the tool would evaluate applicability for substances where dose rate is an influential factor.
2. In addition, triggers to substance-specific assessment as to the suitability of infrequent exposure adjustment include:
    - Genotoxicants
    - Immune reaction promoting chemicals or autoimmunity inducers
    - Substances with non-steady state, known potential for non-linear kinetics or long half-life of elimination (weeks to years)
    - Substances for which a toxic metabolite is produced only under conditions of high exposure
    - Substance with a portal of entry effect and a chronic DNEL based upon an alternate exposure route (but should have an acute DNEL)
    - Developmental hazard potential identified or expected
    - Non-genotoxic carcinogenic hazard identified

[10] Health damaging properties are associated with chemical reactions which take place upon contact with biological tissue.

3.2 Differences Between the TRA and ECHA R15v2016

Since release of the ECETOC TRA v3.1, ECHA has also released an updated version of Chapter R15 Guidelines for Consumer Exposure Assessment (will be referred to as R15v2016). This version of Chapter R15 recognises the difficulty of comparing infrequent and/or short duration exposure estimates to a long-term systemic DNEL value. The updated ECHA R15 guidance approaches the temporal alignment issue by adjusting the hazard aspect of the equation. For infrequent events (<15 days/year), a short-term systemic DNEL can be used rather than the long term systemic DNEL. For short duration events (< 8 hours/day), the systemic DNEL can be increased by a range of factors that vary by event duration. The factors used in these modifications are applied to the DNEL, although it is indicated that reciprocal values could be applied to the exposure estimate for ease of application. The factors are based upon assessment factors used in DNEL derivation, to extrapolate between different toxicology study lengths and different exposure durations within the toxicology studies (Chapter R.8.). A comparison of the factors used in both the TRA and R15 is found in Table 9.

Applying adjustments to the hazard side is an approach to this challenge, but one caution is that it can potentially lead to a disconnect if applied without consideration of the toxicological basis and adjustment factors used in the DNEL derivation. For example, for a 6hour/day inhalation toxicology study, the air concentration may be reduced by a factor of 6/24, that is 0.25, to develop a DNEL (Figure R8.2). If this DNEL is given to the exposure scientist and then back adjusted to a 6 hour duration, it would be multiplied by 1.5 (or exposure multiplied by 0.67) (Table R.15-1), differing from the factor used in its original development. To promote consistency, it would be useful to have this guidance included in Chapter R.8, so that DNELs could be provided along with appropriate supporting information to assist the exposure assessor in proper use.

In order for the user to best assess how the TRA should be applied for a particular assessment, information as to the basis of each approach and how they compare is provided here. Frequency and duration are addressed individually and then combined, as in some cases infrequent uses may have short durations. Factors such as those listed in Inset 1 should be evaluated before applying adjustments for frequency and duration.

Table 9: Comparison of exposure reduction factors

	TRA default	TRA with SCEDs	ECHA R15
Duration	No adjustment	No adjustment	4 factors depending upon time, can apply factor to DNEL or reciprocal to exposure : <0.25 hr/day: 4.5 , reciprocal 0.22 < 1 hr/day: 3, reciprocal 0.33 < 3 hr/day: 2, reciprocal 0.5 < 8 hr/day: 1.5, reciprocal 0.67
Frequency	No adjustment, assumes daily	Banding approach that is equal to or more conservative than frequency value 0.01 - 1	Base on short term systemic DNEL (if this is 28 day study, and it was also the basis of the long term systemic DNEL, and if ECHA default factors were used it would be a factor of 6 lower than the long term systemic DNEL; this would equate to a 0.17 adjustment to the exposure value if compared to the long term systemic DNEL)
Combined duration and frequency adjustment	1	No, same as frequency alone: 0.01 - 1	Yes, exposure multipliers of 0.04 – 1 when combined.

3.2.1 Frequency Approach

R15v2016 proposes an approach that adjusts the long term systemic DNEL value for infrequent exposures (defined as exposure occurring < 15 days per year), but also indicates that for pragmatic purposes the exposure estimate could be adjusted by the reciprocal of this value for the RCR (Table 10).

Table 10: R15 frequency adjustment factors

Frequency	Adjustment Factor – Multiply DNEL by	Reciprocal factor if applied to exposure
>=15 days/year	1	1
<15 days/year	6	0.17

How to use the TRA to derive an estimate consistent with the R15v2016 factors:

A) TRA event values (based on defaults, no application of SCEDs) could be:
   a. Compared to acute DNELs if available
   b. Compared to short term DNELs derived by multiplying the long term systemic DNEL by the appropriate adjustment factor in Table 10
   c. Multiplied by the reciprocal factor in Table 10 and then compared to the long term systemic DNEL

B) For TRA values estimated with frequency banding implemented (application of SCEDs), the banding exposure estimate **or** RCR calculated, based upon the banded exposure, could be multiplied by the factors as shown in Table 11 if it is desired to have a value consistent with R15v2016 guidance:

Table 11: Comparison of TRA frequency band values with R15 frequency adjustment factors

Frequency of use	TRA factor	R15 reciprocal factor (if applied to exposure estimate)	R15/TRA	TRA Scenarios
52 – 365	1	1	1	Default for all TRA scenarios = daily use (exception, 4X/day air fresheners)
15 – 52	0.2	1	5	
12 – 15	0.2	0.17	0.85	
2 – 12	0.04	0.17	4.2	
1 – 2	0.01	0.17	17	

3.2.2 Duration

In chapter R15, the following modifying factors are proposed for duration (Table 12):

Table 12: R15 Duration modifying factors

Duration (hours) of exposure event	Factor to apply to DNEL	Reciprocal factor to apply to exposure estimate
<=0.25	4.5	0.22
<=1	3	0.33
<=3	2	0.5
<=8	1.5	0.67
>8	1	1

These factors are based upon modified Haber's Law. Haber's Law is generally considered to apply to inhalation exposures in units of mg/m^3.

If the assumption is that this factor is to be applied only to inhalation event exposures in mg/m^3, then an equivalent value would be obtained if the TRA event value was multiplied by the reciprocal factors applied in Table 12.

4. ENVIRONMENTAL EXPOSURE ASSESSMENTS

The section below is to provide high-level guidance for improving the exposure estimation by going beyond the defaults set in the REACH R16 Guidance (ECHA, 2016 or the EU Technical Guidance Document (EU TGD, EC 2003). The information provide here may prove most useful when assessing emissions from point sources which have high substance use rates. In addition, it may be valuable when assessing the fate of highly volatile or sorptive chemicals.

While the refinement of the emission estimation can be done in a relatively straightforward manner, this may not be the case for the subsequent modelling of PEC_{Local}. This modelling generally involves higher tier assessment and the corresponding refinements are often case-specific. Hence, the generic advice provided here does not deliver ready-made solutions for assessors. Such solutions are beyond the scope of this document and will most likely require the input of an experience environmental risk assessor.

4.1 Overestimation of PEC_{Local} – Potential Reasons

When assessing emissions from industrial uses which have high substance use rates it is not uncommon that lower tier exposure assessments yield values of PEC_{local} which exceed the Predicted No-Effect Concentration (PNEC). Hence, additional risk assessment steps need to be taken. The reasons underlying the predicted environmental concentration (PEC) overestimation are outlined below and advice is provided on refining the exposure assessment.

The two most common reasons for overestimating PEC_{local} are overly conservative emission estimates and the crude assumptions underlying the PEC_{local} calculation according to the rules laid out in the R16 Guidance and the EU TGD. These two reasons for overestimation PEC_{local} are independent of each other and therefore separate strategies are needed to address them.

4.2 Refining the Emission Estimation

Emission estimates or calculated releases based on site specific monitoring can be used as input to the ECETOC TRA (or, for that matter the other models implementing the R16 Guidance / EU TGD model). They are expressed as emission rates in mass per time. For lower tier exposure assessments, the emission rates E are most frequently modeled as the product of the substance use rate (mass/time) and the so-called release fraction to air, water, and soil. The release factor expresses the fraction of the substance used that is released/emitted to air, water, and soil. According to the latter modelling approach, refinements in the emission estimation may be achieved by reviewing the release factors and / or the geographical distribution (Fmain source).

The ECETOC TRA offers two sets of predefined sets of release factors. For every industrial, professional or consumer use, a collection of parameters, defined as the environmental use conditions, have been assigned to that specific use (ECHA 2010a) These conditions of use, or ‘use descriptors’, are defined as Environmental Release Categories (ERCs), are based on conservative assumptions and have the broadest applicability.

However, these conservative assumptions result in high release fractions and are the least refined approach; as a result, they may frequently lead to overestimations of the PECs (Predicted Environmental Concentrations). As outlined in the ECETOC TRA – Guidance there are several options to improve the emission estimation by selecting the most reasonable collection of 'conditions of use'. These can include i) 'SPERCs', which are standardised, sector-specific lower-tier release factors (Reihlen et al, 2016), ii) customised release factors based on information which is more specific than that underlying SPERCs (e.g. from Best Available Technique (BAT) reference documents, OECD Emission Scenario Documents, site specific information or other) and iii) use of measured emission values.

An additional conservative assumption referenced in the TGD is the Fmain local source, i.e. the fraction of the tonnage which is assumed to be used in a single site, and thus strongly impacts the calculation of the local emissions. For industrial uses, the default value of Fmain local source is 1, meaning that the entire industrial use of a substance takes place in this single site. Values lower than 1 can be used in the assessment if there is information that the substance is used in multiple industrial sites. Constructing a worst-case scenario by basing the assessment on the site with the highest tonnage per use may be helpful for regulatory acceptance of the assessment. Alternatively, an assessment may be site-specific, i.e. with the amounts actually used at a concrete site.

4.3 Refine PEC_{Local} estimation

The PEC_{Local} calculation may lead to overestimation for several compartments because the model makes several assumptions which impart conservatism. The following section informs about strategies which allow to address the PEC_{Local} values. Unfortunately, these refinements cannot be calculated in the ECETOC TRA or the other implementations of the EU TGD. Hence, they need to be done offline.

The estimation of excessive PEC_{Local} in freshwater, freshwater sediment, and in agricultural soil (in case of sewage sludge application to soil) typically may be subsequently re-assessed by using the refined SimpleTreat versions. They may yield a more realistic representation of the degradation processes and lower effluent and finally, lower local concentrations in freshwater, freshwater sediment, or sewage sludge. Particularly the SimpleTreat version for industrial wastewater treatment plant may give more realistic emission estimates for assessing specific sites by parameterising the model with data of the actual wastewater treatment plant.

Another parameter leading to high PEC_{Local} values in soil is the sludge application rate. Under the defaults of the Guidance, the application rate amount to 5 tons/ha, and the application frequency is once per year. In contrast typical values range around 2 tons/ha, in some instances up to 3 tons / ha and under good agricultural practices sewage sludge is applied less frequently. This may be accounted for in discussing the PEC_{Local} for agricultural soil as exemplified in the HERA risk assessment of polyacrylic acid homopolymers and their sodium salts (CAS 9003-04-7, HERA 2014a) and of polyacrylic/maleic acid copolymers and their sodium salts (CAS 52255-49-9, HERA 2014b).

Excessive PEC_{Local} due to emissions to air: Excessive PEC_{Local} in soil may be obtained for two different types of chemicals. In the case of emissions of highly volatile substances, the model assumes that the entire amount emitted is deposited spontaneous to soil and enters the food chain (Russell, 2010). This approach neglects degradation reactions and soil-air partitioning and may eventually lead to excessive exposure in the man-via-

the environment route. This can be addressed by separate modelling of PEC_{Local} in air and soil taking soil-air partitioning into account, air and $PEC_{Local,soil}$.

Finally, according to the calculations presented in ECHA (2016), $PEC_{Localsediment}$ is derived from the corresponding water body concentration ($PEC_{Local, water}$), assuming equilibrium partitioning. The properties of suspended matter are used and it is assumed that this forms the freshly deposited sediment layer. The implied assumption is that sediment-dwelling organisms will only be inhabiting this layer. It should be noted that suspended matter has a lower density (1150 kg_{wwt}/m^3 and 250 kg_{dwt}/m^3) than sediment (1300 kg_{wwt}/m^3 and 800 kg_{dwt}/m^3)[11], which contributes to higher PEC values.

The calculation does not take into account any mixing between bulk sediment and the freshly deposited layer. The benefit of this approach is that can be used for substances that are continuously emitted to the aquatic environment without the need to consider accumulation into the bulk sediment between emission events. In reality, many substances are not continuously emitted into the aquatic environment. Thus, the conservative approach of assuming sorption only to suspended matter without incorporation into the bulk sediment may result in overestimation of exposure. As such, the TRA calculations can be considered as simple Tier 1 screening approach for the sediment compartment.

If rates of biodegradation can be approximated, it is possible to refine $PEC_{Local,sediment}$ by accounting for biodegradation in sediment. Additional processes such as mixing of the suspended solids with bulk sediment (e.g. by bioturbation) and transport of suspended solids to and from the site under consideration may also contribute to $PEC_{Local,sediment}$ being lower than predicted by Tier 1 screening approach. However, these processes are dependent on the hydrology, the sedimentology and sediment biology of the site. The ECETOC task force is unaware of models which allow for accounting for these characteristics and their influence on $PEC_{Local,sediment}$. One possibility to obtain sediment concentrations for risk assessment is to measure sediment concentrations in locations, which, based on the local emission situation, can be considered to represent realistic worst-case conditions.

[11] The divergence in ration between wet weight and dry weight reflects the difference in water content between suspended matter (fraction 0.9) and sediment (fraction 0.8)

ABBREVIATIONS

AISE	Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (International Association for Soaps, Detergents and Maintenance Products)
BauA	German Federal Institute for Occupational Safety and Health
BREF	Best Available Technique (BAT) reference document
Cefic	European Chemical Industry Council
ConsExpo	Consumer Exposure and uptake models
CSA	Chemical Safety Assessment
DNEL	Derived No-Effect Level
Dppe	Dermal personal protection equipment
DU	Downstream Users
DUCC	Downstream Users of Chemicals Co-ordination Group
ECHA	European CHemicals Agency
ENES	Exchange Network on Exposure Scenarios
ERC	Environmental Release Categories
ES	Exposure Scenario
ESCom	Exposure Scenario Communication
ETEAM	Evaluation of Tier 1 Exposure Assessment Models under Reach
EU	European Union
EuPhrac	European Phrase catalogue group
ext-SDS	extended-Safety Data Sheet
FEICA	Fédération Européenne des Industries de Colles et Adhésifs (Association of European Adhesive and Sealant Industry)
GES	Generic Exposure Scenario
GV	General Ventilation
H&S	Health & Safety
LADD	Lifetime Average Daily Dose

LEV	Local Exhaust Ventilation
LRI	(Cefic) Long-range Research Initiative
OC	Operational Condition
OECD	Organisation for Economic Co-operation and Development
OH&S	Occupational Health and Safety
PEC	Predicted Environmental Concentration
PNEC	Predicted No-Effect Concentration
PPE	Personal Protection Equipment
PROC	Process Category
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and restriction of CHemicals
RIP	REACH implementation project
RMM	Risk Management Measure
RPE	Respiratory Protection Equipment
SCED	Specific Consumer Exposure Determinant
SpERCs	Specific Environmental Release Categories
SVP	Saturated Vapour Pressure
SWED	Specific Worker Exposure Determinants
TGD	Technical Guidance Document
TRA	Targeted Risk Assessment
TWA	Time Weighted Average
UD	Use Descriptors
UM	Use Map
US EPA	(US) Environmental Protection Agency
VP	Vapour pressure

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APPENDIX 1: SUMMARY OF ECETOC RESPONSE TO THE INITIAL PUBLICATION OF E-TEAM FINDINGS (DECEMBER 2015)

A major study of the available REACH Tier 1 worker exposure models has recently been published (BAuA, 2015) (http://www.baua.de/en/Publications/Expert-Papers/F2303-D26-D28.html). The project, known as the ETEAM, was sponsored by the German Federal Institute for Worker Health and Safety (BAuA), with the intention of comparing measured exposure data against the modelled estimates from the commonly encountered REACH Tier 1 worker models (TRA, MEASE, Stoffenmanager and EMKG). ECETOC participated in the Advisory Board to the project. Although the project is the largest of its type, it has been hampered by its inability to identify large numbers of representative exposure measurements for the range of situations demanded by REACH: measured data have only been identified for 18 of the 29 PROCs described by REACH; only 11 PROCs have more than 20 data points associated with them; and of those, only 5 PROCs have associated data points of >150 samples. Because complex analyses require a lot of data (for example, covering the range of volatilities and use characteristics covered by the TRA), then this severely limits the extent to which any reliable conclusion can be drawn by the ETEAM and particularly so for those situations where fewer than 75-100 data points are available. A more extensive analysis of the ETEAM findings for the TRA can be found on the TRA webpage (www.ecetoc.org/tra).

Despite these limitations, it is ECETOC's opinion that the ETEAM report generally serves to confirm that the TRA is providing reliable estimates of worker exposures for use under REACH. Indeed, the E-Team analyses appear to indicate that the TRA is an inherently conservative model and hence eminently suitable for application at Tier 1 of REACH. However, the ETEAM analyses also identify that there are elements of the TRA that may benefit from review and possible revision (such as the TRA's ability to predict exposures to substances of very low volatility and the role that extract ventilation can have in reducing exposures). In these areas, ECETOC will be working with the other participants of the E-Team to better understand the characteristics of the database and the basis of the researcher's findings.

ECETOC will continue to review the performance of the TRA and to make revisions to the model where relevant. In this context, it will continue to work with and communicate the findings of the ETEAM project with the TRA community and to update the TRA and its supporting FAQs should reliable data becomes available that demonstrate serious shortcomings in the performance of the TRA.

Background

The ETEAM project, sponsored by the German Federal Institute for Worker Health and Safety (BAuA) aims to compare and contrast the different REACH Tier 1 worker exposure assessment models (the TRA, MEASE, Stoffenmanager and EMKG models) in terms of the nature of their predictions, scope of application, functionality and user-friendliness. The EU REACH Regulation covers all uses of all substances and applies the Use Descriptor (UD) as a mechanism for distinguishing the different exposures that are associated with different types of worker, consumer or environmental use. For workplace uses, REACH allocates different Process Categories (PROCs) to distinguish different use: a total of 29 PROCs have been described of which 26 are addressed by the TRA (ECETOC, 2009; ECHA, 2010a)

To achieve the aims of the ETEAM, the researchers set out to create a database of measured data against which the predictions of the various models being evaluated could be compared. Clearly, in order that research objectives could be met, such a database must be able to cover the key uses of chemicals as described by the available PROCs as well as a range of chemical types (solids, liquids and gases). In order to meet such an aim, data were submitted by 11 major institutions, including those from the US. Several thousand sets of measured data were offered by these institutions to the ETEAM researchers. In order to ensure that only data of a high quality were included in the database, the researchers developed quality criteria which the data were required to meet (and which relate both to the integrity of the measurements as well as supporting contextual data that enable such data to be interpreted). However, the consequence of applying the criteria to the data were that only a small fraction of the data submitted were deemed acceptable for inclusion in the database.

Table 3.8 below is taken from the ETEAM Substudy Report on the External Validation Exercise (BAuA, 2015) and summarises the distribution of the data that were accepted into the database versus their origin (task/activity/operation) in terms of how such data are likely to be described under REACH (their PROCs).

Table 3.8: Individual measurement data by allocated PROC code

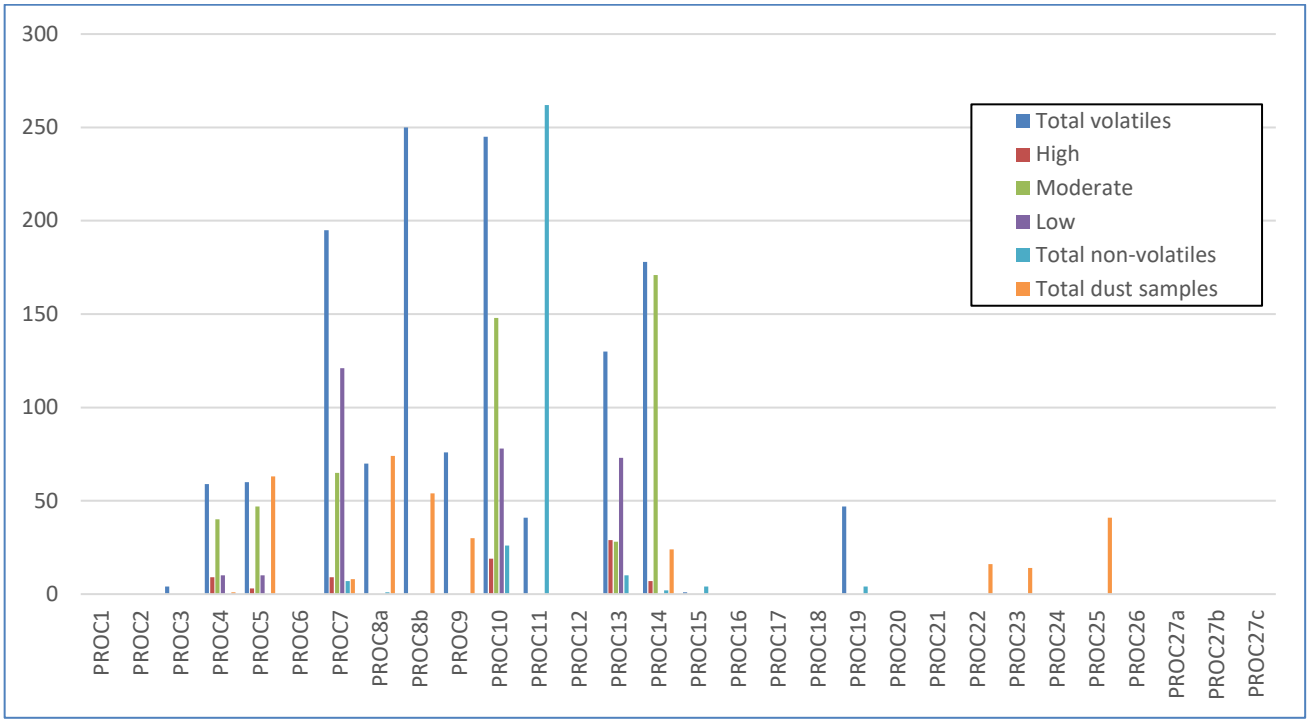
	PROC codes																		
Exposure category	3	4	5	7	8a	8b	9	10	11	13	14	15	19	21	22	23	24	25	Total
Non-volatile liquids[1)]	0	0	0	7	1	0	0	26	262	10	2	4	4	0	0	0	0	0	316
Volatile liquids[2)]	4	59	60	195	70	250	76	245	41	130	178	1	47	0	0	0	0	0	1356
Metal abrasion	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	87	0	87
Metal processing	0	0	0	0	0	0	0	0	0	0	0	0	0	0	16	14	0	41	71
Powder handling	0	1	63	8	74	54	30	0	0	0	24	0	0	0	0	0	0	0	254
Wood processing	0	0	0	0	0	0	0	0	0	0	0	0	0	14	0	0	0	0	14
Total	4	60	123	210	145	304	106	271	303	140	204	5	51	14	16	14	87	41	2098

[1)] non-volatile liquids are defined as liquids with a vapour pressure (at room temperature) ≤10 Pa.
[2)] volatile liquids are defined as liquids with a vapour pressure (at room temperature) >10 Pa.

The expectations for any exposure model are that its predictions are reliable across a full range of substances types (i.e. different physico-chemical forms such as dusts, gases and vapours), as well as the routes and forms of exposure that the use of such substances can be expected to result in (for example, inhalation and dermal exposures and exposures to dusts, aerosols and vapours/gases). A further expectation is that the models might reasonably be expected to account for the commonly encountered OCs and RMMs, as well as whether the substance is encountered in the pure form or as part of a mixture. Table 3.8, however, clearly shows that not only are several of the key PROCs not represented in the database, but that the database is dominated by measurements of volatile liquids and that for many PROCs no or few data exist against which any comparison might be made. It is also to be noted that because of the shortcomings of how data have been recorded, the ETEAM has not been able to provide a breakdown of the different substance types within an exposure category for all substance types e.g. nature of dustiness.

Figure 1 below, which is based on the data contained in Appendix 4 of work package D15 (BAuA, 2015), further illustrates the lack of completeness of the database in terms of its ability to describe the distribution of exposure with industry (PROCs).

Figure 1: Representativeness of E-Team Database



When seen in the context of the need for data covering all uses and substance types, it can clearly be seen that the ETEAM database only addresses a small fraction of the need. Only 15 of the 25 PROCs have data associated with them and only 11 of these have more than 20 data points. Moreover, only 5 PROCs are associated with >150 samples with the vast majority of these being for volatile substances (but where no information is provided on the nature of these volatilities). However, for any one PROC, there are potentially well over 100 different estimates that can result from different combinations of volatility/dustiness; use type (industrial/ professional), presence/absence of exposure controls; handling pure/diluted substance; exposure duration; etc. Within this context, it can clearly be seen that the database is insufficient for drawing broad conclusions on the 29 PROCs described in ChR12 although it has the potential to provide a basis for a preliminary analysis for volatile substances for PROCs 7, 8b, 10, 11 and 14.

Despite these limitations, Table 3.48 of the D15 Report (reproduced below) provides an insight into the inherent conservatism of the TRA's base estimates. It shows that for (all) volatile substances, the TRA 'over predicts' in the c.9% of cases where 'no LEV' is encountered although the ETEAM analyses do not provide an analysis by volatility type so this value may not be uniform across volatility bands. This finding contrasts with an over-prediction rate of 67% where local exhaust ventilation (LEV) is encountered and has been applied to the base estimate. This contrast may be due to the actual effectiveness of LEV in the workplaces where the measurements were obtained being low and much less than the values assumed within the TRA and which accords with the findings of wider studies on the effectiveness of LEV (HSE, 2011; ECETOC, 2012). Another explanation could be that because of the nature of the contextual information supporting the data, the researchers' allocation of LEV as a control type was misplaced. Although Table 3.48 appears to indicate that the TRA may be insufficiently conservative with respect to exposures to dusts, the strength of the analysis is low (comparatively few samples available when compared to those required) and biased (the available samples are clustered around just a few PROCs) but clearly warrants follow-up using a larger and more representative dataset.

Table 3.48 Percentage of (individual) measurements above the tool estimates (%M>T) by tool input parameter factors

	Factor															
	Dustiness			Vapour pressure			Domain		LEV				Concentration in mixture			
Exposure Category	High	Med	Low	High	Med	Low	Professional	Industrial	LEV	LEV/ out [1]	No LEV	No LEV/ out[1]	<1%	1-5%	6-25%	>25%
ECETOC TRAv2 (%M>T)/ (number of measurements)																
Volatile liquids	*	*	*	37 (n=320)	29 (n=886)	18 n=(131)	5 (n=374)	40 (n=963)	67 (n=542)	0 (n=15)	5 (n=772)	0 (n=8)	43 (n=7)	2 (n=296)	30 (n=364)	42 (n=670)
Metal abrasion	*	66 (n=41)	20 (n=41)	*	*	*	0 (n=4)	45 (n=78)	74 (n=35)	*	19 (n=47)	*	*	*	0 (n=7)	47 (n=75)
Powder handling	35 (n=51)	25 (n=194)	100 (n=1)	*	*	*	13 (n=92)	35 (n=162)	13 (n=107)	*	37 (n=147)	*	*	*	0 (n=8)	28 (n=246)
ECETOC TRAv3 (%M>T)/ (number of measurements)																
Volatile liquids	*	*	*	43 (n=320)	35 (n=886)	21 (n=131)	6 (n=374)	47 (n=963)	74 (n=542)	0 (n=15)	9 (n=772)	0 (n=8)	57 (n=7)	3 (n=296)	43 (n=364)	45 (n=670)
Metal abrasion	*	68 (n=41)	20 (n=41)	*	*	*	0 (n=4)	46 (n=78)	74 (n=35)	*	21 (n=47)	*	*	*	0 (n=7)	48 (n=75)
Powder handling	35 (n=51)	27 (n=194)	100 (n=1)	*	*	*	8 (n=92)	40 (n=162)	13 (n=107)	*	39 (n=147)	*	*	*	0 (n=8)	29 (n=246)

It is ECETOC's view, therefore, that while the ETEAM project set out to compare the performance of different REACH models, the nature of the ETEAM database is inadequate to draw categorical conclusions as it appears to lack data for some substance types and does not cover many of the major uses of key chemical types. Moreover as the ETEAM project only examined the models in isolation and not within the context of how the models are intended to be applied under REACH e.g. accounting for the impact that support structures such as Use Maps have on reducing the variability of predictions and improving consistency across users, then the ETEAM's analyses have not addressed key areas of interest for the users of such tools: for example, the relationship of the tools to the efficient (and consistent) development of Chemical Safety Assessments (CSAs) and Exposure Scenarios (ESs); the communication of ESs and the ability to implement and scale the exposure control advice that they contain.

In summary, it is ECETOC's opinion that the ETEAM analyses are insufficiently reliable, powerful or detailed to enable developers of the various Tier 1 REACH models to identify where/how their models should be further improved e.g. any need to refine the estimates or assumptions underpinning how any OC and RMM may affect the predictions. The ETEAM has now made available its database and ECETOC will be examining it in more detail in order to determine the extent to ECETOC's concerns can be accounted for and meaningful conclusions drawn from it. In this respect ECETOC will continue to review the performance of the TRA and any new information that becomes available on it. It also remains ECETOC's intention to make further revisions to the TRA when substantive new knowledge becomes available on its performance under REACH.

APPENDIX 2: ECETOC RE-ANALYSIS OF ETEAM DATABASE

Re-analysis of the ETEAM Database for the ECETOC TRAv3 Model

Bachler G[1], Barone N[2], Keller D[3], Money C[4], Noij D[5], Tibaldi R[2]

[1]Shell Health, Shell International B.V., The Hague, The Netherlands.
[2]ExxonMobil Biomedical Sciences, Inc., Annandale, New Jersey, U.S.
[3]Henkel AG & Co. KGaA, Düsseldorf, Germany
[4]Cynara Consulting, Hampshire, United Kingdom
[5]Dow Chemical Company, Terneuzen, Netherlands

Background

- In 2015 an ETEAM study (BAuA, 2015) evaluated Tier 1 worker exposure models.
- Their database measurements and assumptions used to validate model estimates are now available.
- ECETOC took the opportunity to examine the ETEAM findings, assess the database, and identify possible areas of improvements to TRA worker exposure estimates.

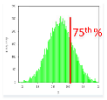
Objectives

ECETOC investigated several questions:

- Can ETEAM data analysis be accurately re-constructed?
- Does the database contain sufficient contextual information for PROC choices?
- Do scenarios cover situations considered within the TRA domain?
- How were Use Descriptors applied to develop the TRA estimate? e.g. per Use Maps
- Was the method of validation analysis by ETEAM appropriate for the TRA?
- Are ETEAM estimates 'accurate'?
- What improvements might be considered for TRA?

Method

1. ECETOC Scientific Committee endorsed re-analysis in March 2016; TRA working groups (WG) formed.
2. ETEAM access database converted into Excel to aid analysis and transparency. Parameters included:
   - scenario information
   - sample information
   - ETEAM TRA input variables and TRA exposure estimates
   - 75th percentiles calculated for ETEAM scenarios with datasets and single data points to compare with TRA 75th percentile (P75)estimates
   - sample data
   - number of samples for each scenario (N)
   - minimum (MIN), maximum (MAX), arithmetic mean (AM), geometric mean (GM), geometric standard deviation (GSD)



3. TRA WG preliminary analysis:
   - Powder handling and metal abrasion scenario data limited
   - Volatile substance data more extensive
   - Focused on PROCs 4, 5, 7, 13, 14, and 19 due to ETEAM report of underestimation
4. Scenarios by PROC allocated to 3 teams of REACH worker exposure assessors
5. Judgments and comments of assessors recorded and consolidated
6. Comparisons to ETEAM decisions and TRA WG judgments analyzed

Findings

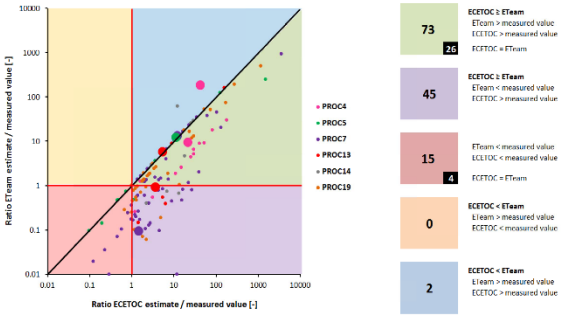
- ETEAM database contains 1673 sample data points
  - –These derive from 337 scenarios total in database
  - – 64 of the 337 scenarios have datasets with ≥ 6 data points
- Of the 337 scenarios, 282 relate to volatile substances, 30 powder handling, 25 were metal abrasion
- ETEAM database contains sufficient information to re-construct estimates
- ETEAM Methodology for TRA model validation found to be problematic:
  1. ETEAM analysis compared single measurements to TRA estimates
     - –165 of the 337 scenarios (~50%) contained only a single measurement
     - TRA provides a P75 exposure prediction for a work group activity
     - –ETEAM analysis should have compared the scenarios with datasets to TRA P75 estimates for relevant work group activities
  2. ECETOC TRA WG aggregated the single measurements in same scenarios to determine P75 values. These were then compared to the TRA estimate.
  3. For many scenarios, use and exposure descriptor choices were inaccurate
     - –ETEAM assignments often did not match database contextual information
     - Particularly for PROCs, LEV assumptions, and duration
     - –ECETOC TRA WG applied a Consensus-based approach for Use Descriptor decisions

Category / Proc	Scenarios	Samples	TRA <p75	Team Assigned
Metal abrasion	**25**	**82**	**15**	
2a High (mechanical) energy work-up of substances bound in/on materials and/or articles	25	82	15	
Powder handling	**30**	**248**	**16**	
4 Chemical production where opportunity for exposure arises	1	1	0	
5 Mixing or blending in batch processes	6	63	3	
7 Industrial spraying	1	2	0	
8 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	1	30	0	
14 Tabletting, compression, extrusion, pelletisation, granulation	1	24	3	
08a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	12	39	7	
08b Transfer of substance or mixture (charging and discharging) at dedicated facilities	8	56	3	
Volatile Liquids	**282**	**1343**	**124**	
3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	2	4	1	
4 Chemical production where opportunity for exposure arises	25	59	11	Team A
5 Mixing or blending in batch processes	13	56	9	Team B
7 Industrial spraying	63	195	47	Team C
9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	7	76	1	
10 Roller application or brushing	45	245	21	
11 Non industrial spraying	9	23	0	
13 Treatment of articles by dipping and pouring	35	130	16	Team A
14 Tabletting, compression, extrusion, pelletisation, granulation	10	188	5	Team C
15 Use as laboratory reagent	1	1	1	
20 Manual activities involving hand contact	40	47	14	Team B
08a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	12	70	2	
08b Transfer of substance or mixture (charging and discharging) at dedicated facilities	22	249	6	
Grand Total	**337**	**1673**	**155**	

Re-Analysis Results

- 184 scenarios were re-analyzed by 3 teams of experienced REACH workplace exposure assessors
- 135 scenarios determined as inside domain of TRA (27% found outside TRA domain)
- 118 cases where TRA WG disagreed on ETEAM allocation of TRA input parameters
- 90 cases where comparisons to measured values by TRA WG and ETEAM agreed on the conclusion as either under or overestimate

Figure below compares ECETOC TRA WG estimates and ETEAM TRA estimates against measured values for 135 scenarios



- Large dots represent 6+ data points
- Dots on diagonal: 30 scenarios where ECETOC TRA WG and ETEAM estimates same
- Dots in red box: scenarios where TRA estimates not conservative (<measured values)
  - in the 15 scenarios where measured P75 > TRA P75; there were fewer than 6 data points
- Dots below diagonal represent scenarios where ECETOC TRA WG estimate was greater than ETEAM estimate (103 cases)
- 2 cases where TRA WG estimates were lower than original ETEAM predictions
- ETEAM errors tended to bias to lower estimate

Conclusions

- Many instances found where datasets have few samples and not sufficiently robust to draw critical conclusions.
  - –A few datasets appear to heavily weigh on overall findings
  - –No 'statistical test' applied to determine if the datasets can be considered representative
- The ETEAM database contains cases where REACH Use Descriptors were incorrectly applied.
  - –This materially affects the nature of the associated ETEAM findings
  - –Use map resources can aid ETEAM in assigning proper TRA parameters
- Based on the preliminary findings presented above suggest ETEAM results on TRA underestimation of some PROCs, is premature and less severe than reported by ETEAM
- Conclusions in ETEAM report need further examination

Next Steps

- ECETOC will continue to review new information that is relevant to ensuring the TRA remains accurate and fit-for-purpose for use under REACH
  - –Discuss findings with ETEAM investigators
  - –Explore options to gain additional measurement data
  - –Develop 2017 plans for future TRA update

References

- BAuA, 2015, Evaluation of Tier 1 Exposure Assessment Models under REACH (eteam) Project (http://www.baua.de/en/Publications/Expert-Papers/F2303-D26-D28.html)
- European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), *Targeted Risk Assessment.* Technical Report number 93, European Centre for Ecotoxicology and Toxicology of Chemicals, Brussels, Belgium, 2004.
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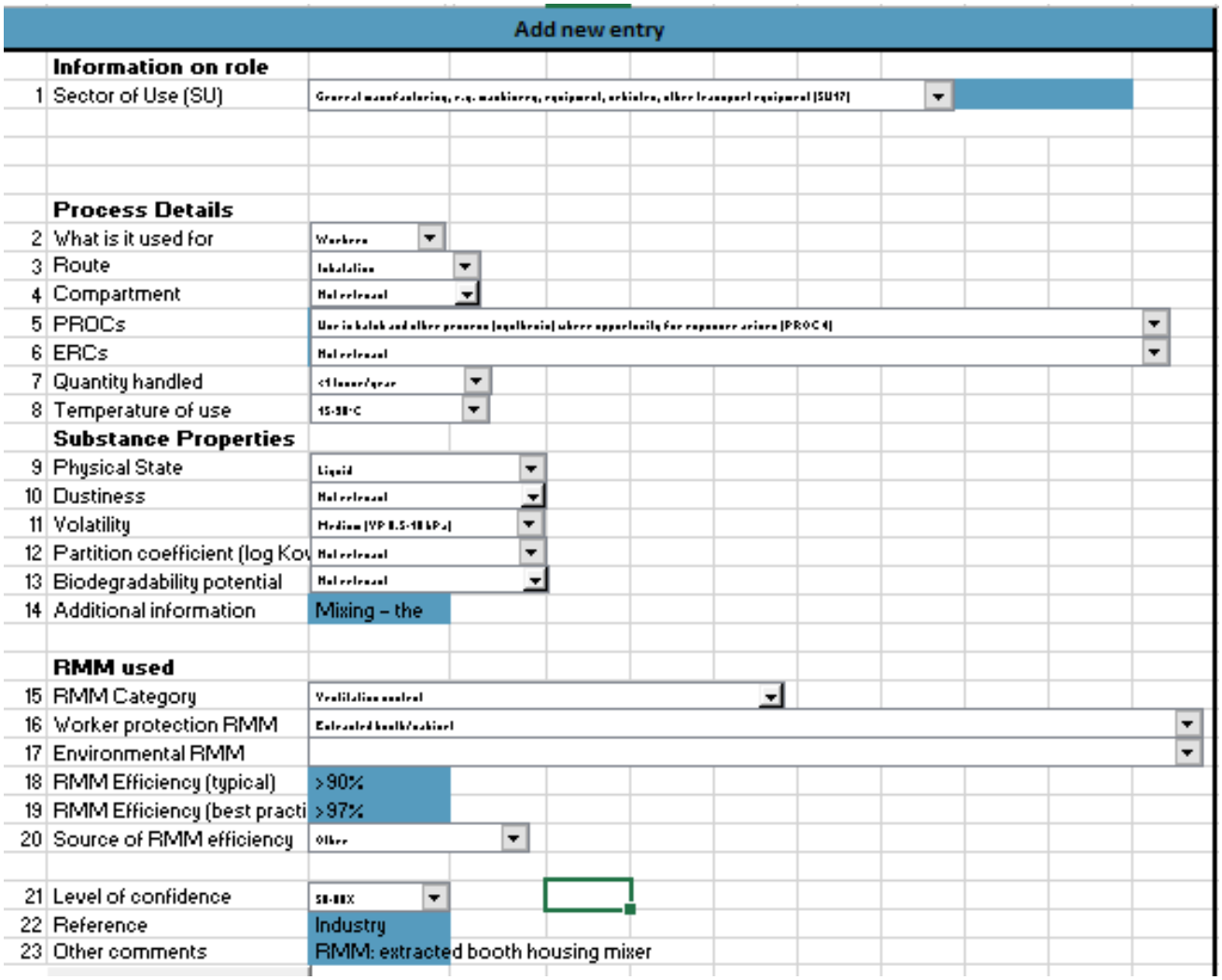
- European Chemicals Agency (ECHA), 'Guidance on information requirements and chemical safety assessment Chapter R.12: Use Description' (v.3, Dec 2015)
- European Chemicals Agency (ECHA), 'Guidance on information requirements and chemical safety assessment Chapter R.14: Occupational exposure estimation' (v3, Aug 2016)

Further information: Allan Poole, *Secretary General ECETOC, Tel: 32 2 663 3816, Email: alan.poole@ecetoc.org*

APPENDIX 3: POSSIBLE OUTLINE FOR AN RMM REPORTING TEMPLATE

The following template was applied in the CEFIC-LRI B15 study to obtain information on the effectiveness of RMMs used to control workplace exposures both to humans and the environment.



	Add new entry	
	Information on role	
1	Sector of Use (SU)	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment (SU17)
	Process Details	
2	What is it used for	Workers
3	Route	Inhalation
4	Compartment	Not relevant
5	PROCs	Use in batch and other process (synthesis) where opportunity for exposure arises (PROC 4)
6	ERCs	Not relevant
7	Quantity handled	<1 tonne/year
8	Temperature of use	15-20°C
	Substance Properties	
9	Physical State	Liquid
10	Dustiness	Not relevant
11	Volatility	Medium (VP 0.5-10 kPa)
12	Partition coefficient (log Kov	Not relevant
13	Biodegradability potential	Not relevant
14	Additional information	Mixing – the
	RMM used	
15	RMM Category	Ventilation control
16	Worker protection RMM	Extracted booth/cabinet
17	Environmental RMM	
18	RMM Efficiency (typical)	>90%
19	RMM Efficiency (best practi	>97%
20	Source of RMM efficiency	Other
21	Level of confidence	50-80%
22	Reference	Industry
23	Other comments	RMM: extracted booth housing mixer

In terms of the 23 headings, further explanation on their intended scope and content is given below.

	Quick guidance on selecting the case study parameters
1	Please select the most appropriate sector for the industry the RMM is applied in
2	Please select if the RMM aims at protecting worker health or the environment
3	The relevant route of exposure. If both, please fill in two entries. Menu will be unavailable for environmental RMM
4	The relevant environmental compartment. If more than one please fill in separate entries. Menu will be unavailable for worker RMM
5	Please select the appropriate PROC for the process the RMM is applied in. Menu is irrelevant for environmental RMM See relevant ECHA guidance R.12.
6	Please select the appropriate ERC for the process the RMM is applied in. Menu is irrelevant for worker RMM See relevant ECHA guidance R.12.
7	Select the annual quantity of the substance used in the process examined
8	Select the temperature range of the process.
9	Please select the physical state of the substance at the process temperature
10	Please see examples on dustiness levels provided. Menu will only be available if solid is selected at 9
11	Please use guidance on Vapour Pressure (in operating T) proposed. Menu will only be available if liquid is selected at 9
12	Please select according to substance's logKow if available. Menu will only be available for environmental RMM
13	Please classify biodegradability according to OECD tests for ready/inherent biodegradability. Menu will only be available for environmental RMM
14	Please add any additional information on the substance or the conditions of use (e.g. substance name, manual handling)
15	Selecting an RMM category will auto-fill in menu 16
16	Please select the most appropriate RMM from the list.
17	Please select the most appropriate RMM from the list.
18	(If available) enter the typical RMM efficiency (50th percentile)
19	(If available) enter the best practice RMM efficiency (highest attainable value)
20	Please select the source of the RMM efficiency. If based on own measurements, select "Other" and explain in 22
21	This is subjective, but in general peer-reviewed studies and company data would be at the highest levels
22	Please provide the full reference of the source of the case study
23	Provide any other information you consider relevant (e.g. reasons for uncertainty, details on RMM application)

MEMBERS OF THE TRA STEERING TEAM

J. Tolls (Chair)	Henkel D – Düsseldorf
D. Keller	Henkel D – Düsseldorf
C. Money	Cynara Consulting UK – Brockenhurst
D. Noij	Dow NL – Terneuzen
C. Rodriguez	Procter & Gamble B – Strombeek-Bever
F. Schnöder	DuPont D – Neu-Isenburg
R. Tibaldi	ExxonMobil USA – Annandale, NJ
J. Urbanus	Shell B – Brussels
R. Zaleski	ExxonMobil USA – Annandale, NJ
A. Brousse	ECETOC (Human Health Sciences Manager) B – Brussels
O. de Matos	ECETOC (Secretary General from September 2017) B – Brussels
A. Poole	ECETOC (Secretary General, retired September 2017) B – Brussels

Additional contributions

The TRA Steering Team are indebted to G. Bachler of Shell and S. Jacobi of Albemarle for their contributions to this initiative.

MEMBERS OF THE SCIENTIFIC COMMITTEE

B. van Ravenzwaay (Chairman) Senior Vice President - Experimental Toxicology	BASF D – Ludwigshafen
R. Bars Team Leader, Toxicology Research	Bayer CropScience F – Sophia Antipolis
P. Boogaard Global Discipline Lead & Manager Toxicology	Shell Health NL – The Hague
P. Botham [#] Principle Science Advisor	Syngenta UK – Bracknell
A. Flückiger Chief Occupational Health Officer	F. Hoffmann - La Roche CH – Basel
H. Greim Institute of Toxicology and Environmental Hygiene	Technical University München D – München
J. Hermens [#] Associate Professor, Institute for Risk Assessment Sciences	University of Utrecht NL – Utrecht
H. Hollnagel Regulatory Toxicologist	Dow CH – Horgen
P. Lemaire [#] Head of Product Stewardship and Sustainable Development	Total Fluides F – Paris La Défense Cedex
L. Maltby Professor of Environmental Biology	University of Sheffield UK – Sheffield
M.L. Meisters Manager Health and Environmental Sciences EMEA	DuPont de Nemours B – Mechelen
S. Mukhi [#] Global Leader, Risk Assessment	Honeywell USA – Morris Plains, NJ
M. Pemberton Director	Systox UK – Wilmslow

[#] From September 2017

C. Rodriguez*	Procter and Gamble
Principal Toxicologist, Corporate Central Product Safety	B – Strombeek-Bever
G. Sanders #	Givaudan
Environmental Toxicology Manager	CH – Vernier
G. Swaen #	Maastricht University
Associate Professor	NL – Maastricht
J. Tolls*	Henkel
Director Environmental Safety Assessment	D – Düsseldorf
K. van Leeuwen	KWR Watercycle Research Institute
Principal Scientist	NL – Nieuwegein
E. van Miert #	Solvay
TERA 2 Manager	B – Brussels
R. Zaleski*	ExxonMobil
Exposure Sciences Section Head	USA – Annandale, NJ

From September 2017

* Responsible for peer-review

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Responsible Editor:
Mr Olivier de Matos
ECETOC AISBL
Av. E. Van Nieuwenhuyse 2 (box. 8)
B-1160 Brussels, Belgium
VAT: BE 0418344469
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